Effectiveness of oral healthcare protocols for preventing and treating carious lesions in mixed-dentitions

Leandro Augusto Hilgert

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Thesis – Radboud University Nijmegen – with summary in Dutch and Portuguese

ISBN: 978-94-6259-939-0

Printed by: Ipskamp Drukkers B.V.

Effectiveness of Oral Healthcare Protocols for Preventing and Treating Carious Lesions in Mixed-Dentitions

Proefschrift

ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus
volgens besluit van het college van decanen
in het openbaar te verdedigen op
donderdag 10 december 2015
om 14.00 uur precies

door

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geboren op 5 august 1981
te Passo Fundo, Brazilië

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Effectiveness of Oral Healthcare Protocols for Preventing and Treating Carious Lesions in Mixed-Dentitions

Doctoral thesis

to obtain the degree of doctor
from Radboud University Nijmegen,
on the authority of the Rector Magnificus
according to the decision of the Council of Deans
to be defended in public
on Thursday, 10 December 2015
at 14.00 hours

by

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The research presented in this thesis is the result of the collaboration project between the University of Brasília, School of Health Sciences, Department of Dentistry, Brasília, Brazil and the Radboud University Medical Centre, College of Dental Sciences, Department of Oral Rehabilitation in Nijmegen, The Netherlands.

'Luckless that I am!' said Don Quixote, hearing the sad news his squire gave him (on the loss of Quixote's teeth); 'I had rather they despoiled me of an arm, so it were not the sword–arm; for I tell thee, Sancho, a mouth without teeth is like a mill without a millstone, and a tooth is much more to be prized than a diamond.'

(CERVANTES, 1605)

ORIGINAL PUBLICATIONS

This PhD thesis is based on the following original publications.

1. Hilgert LA, de Amorim RG, Leal SC, Mulder J, Creugers NHJ, Frencken JE. Is high-viscosity glass-ionomer-cement a successor to amalgam for treating primary molars? Dent Mater 2014; 30: 1172-1178.

2. Hilgert LA, Frencken JE, de Amorim RG, Mulder J, Leal SC. A study on the survival of primary molars with intact and with defective restorations. Int J Paediatr Dent 2015 (in press)

3. Hilgert LA, Leal SC, Mulder J, Creugers NHJ, Frencken JE. Caries-preventive effect of supervised tooth brushing and sealants. J Dent Res 2015;94:1218-24.

4. Hilgert LA, Leal SC, Freire GML, Mulder J, Frencken JE. 3-Year survival rates of retained composite and ART sealants using two assessment criteria.

5. Hilgert LA, Leal SC, Bronkhorst E, Frencken JE. Long-term effect of supervised tooth brushing on levels of plaque and gingival bleeding among schoolchildren.

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CHAPTER 1

INTRODUCTION, RATIONALE AND AIMS OF THE PHD THESIS

Abstract

Chapter 1 provides background information regarding the dental caries situation in schoolchildren of Paranoá, a deprived suburban area of Brasília, the capital city of Brazil. The Paranoá Study is introduced, the rationale and the aims of implementing oral healthcare protocols in schoolchildren are discussed, both for managing existing carious lesions in the primary dentition and for preventing new carious lesions in the mixed-dentition. At present, oral healthcare protocols in Paranoá comply with the established status quo, in which conventional restorations are performed to treat cavitated dentine carious lesions. Paradigm shifts, new materials and new trends in dentistry that may affect these oral healthcare protocols are presented. Ways of preventing the development and/or progression of carious lesions in permanent molars of schoolchildren are critically reviewed. The chapter concludes with the primary and specific aims of this PhD research.

1.1 Introduction

Dental caries is the most common oral disease, and billions of people worldwide live with untreated cavitated dentine lesions in their dentition (1). Despite the decline in caries experience in the last decades, which occurred mainly in developed countries, dental caries remains a major concern for the dental profession and public health authorities (2,3). For children, the situation seems to be even more alarming, as early childhood caries, instead of decreasing, is increasing beyond the targeted 11%, as proposed by the USA governmental programme 'Healthy People 2010' (3).

In Brazil, the national epidemiological survey, performed in 2010, (SB Brasil 2010) (4) revealed a mean dmft score of 2.3 in 5-year-old children. In 12-year olds, caries prevalence (cavitated dentine carious lesion) was 56% and the mean DMFT score was 2.1. Despite the high level of caries prevalence and experience, these findings were lower than the results of a national epidemiological survey carried out 7 years earlier. However, in 5 year-old children, 80% of the cavitated dentine carious lesions were found untreated, a finding that was not different from the one reported by the 2003 National Oral Health Survey (5). These findings indicates the lack of access of children to adequate oral healthcare and, most importantly, the inability of the oral health programmes currently available in the country to provide appropriate coverage and care.

Although some studies have shown that the majority of primary teeth with untreated cavitated dentine carious lesions may exfoliate without problems (6,7), severe dental caries may progress to fistula or abscess, which are usually associated with pain and, in most cases, lead to a premature tooth loss. These conditions, especially toothache and history of tooth extraction, have shown to impact negatively on both the family and child's quality of life (8). Moreover, studies have shown that severe cases of untreated cavitated dentine carious lesions are related to child hospitalisation and visits to emergency care units (9,10) and to bad performance and missing days at school (11-13).

Another aspect that should be taken into account when analysing the caries prevalence status among Brazilian children is the unequal distribution of the disease, as 20% of children present 60% of the dental caries (14). This fact is highly influenced by socio-economic factors (15). Furthermore, in Brazil, an association between severity of dental caries in primary teeth and type of school (public or private) that children attended has been reported. Children that

attended public schools showed higher severity scores of dental caries than those in private schools (16).

Taking the above factors into consideration in Brazil, ways of increasing children's access to oral health service should be explored, especially for those who are living under conditions that make them vulnerable, in addition to providing them with palliative, preventive and restorative oral healthcare. An attempt to achieve this purpose was carried out in public schools of a low socio-economic suburban area of Brasília, called Paranoá.

1.2 The Paranoá Study

According to the 2010 census, Paranoá has a population of 37,213 people and a mean monthly per capita income of R$ 706.84 (approximately €208.00 – using the exchange rate of March 2015). Its Human Development Index (HDI) for 2010 was 0.731, which is below the 0.824 HDI level for the whole of Brasília (17). Being one of the poorest areas of Brasília, Paranoá was elected for research purposes as part of an agreement signed between the University of Brasília and the local government's Educational and Health Department to improve living and health conditions in the suburban area.

The Paranoá Study was designed in 2008, with the main aims of assessing the cost effectiveness of three different oral healthcare protocols for managing cavitated dentine carious lesions in primary molars and of preventing carious lesions in the permanent dentition. After obtaining study approval from the University of Brasília Ethics Committee, an epidemiological survey was carried out in 2009. The major components of the so-called 'Paranoá Study' and related relevant aspects of oral healthcare protocols under study are shown in Figure 1.1.

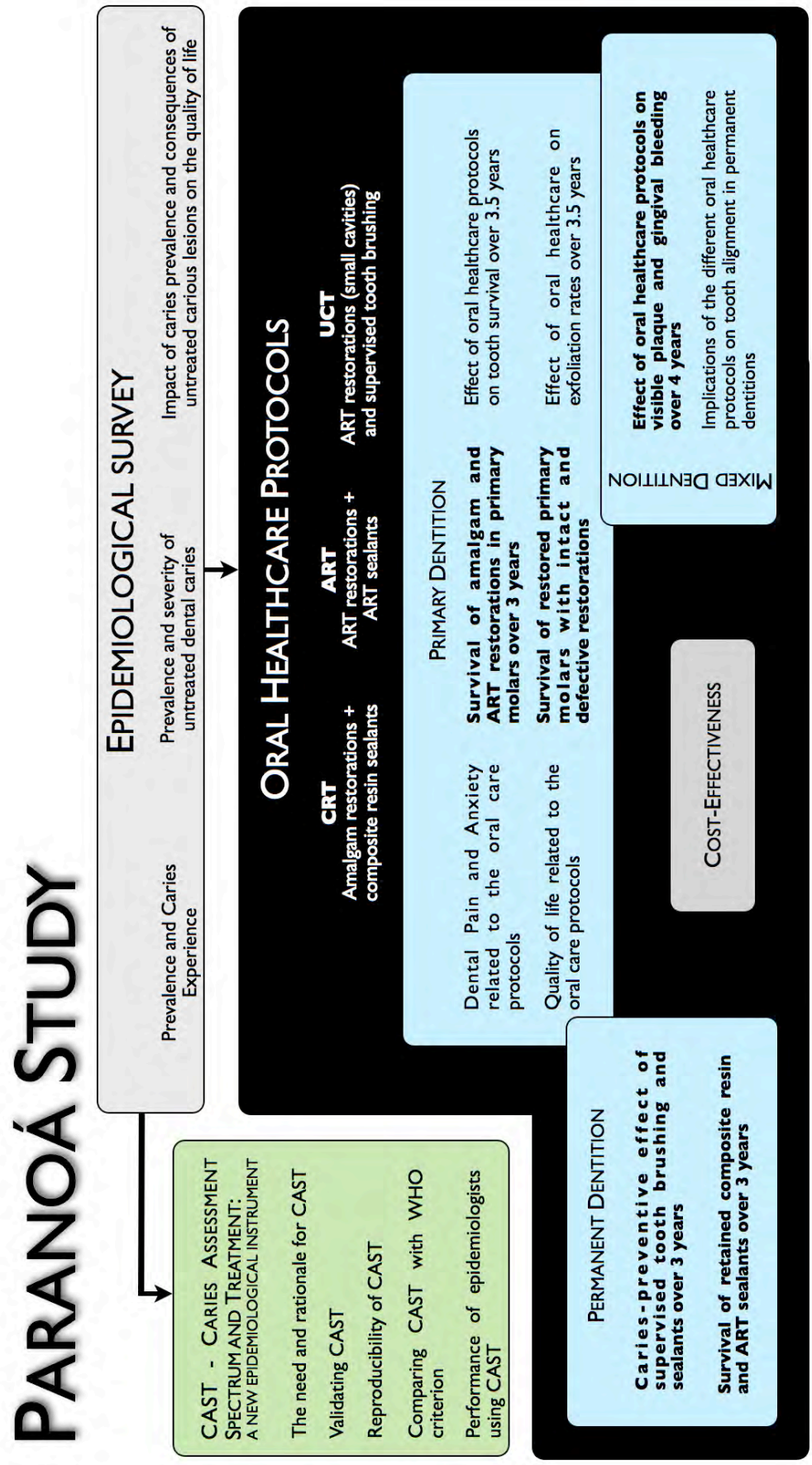

Figure 1.1 – Paranoá Study overview. The topics of the study typed in bold are presented in this PhD thesis.

The epidemiological survey was conducted in all six public primary schools in Paranoá using the 'International Caries Detection and Assessment System II' (ICDAS II) for caries detection and the pufa/PUFA index for recording the consequences of untreated cavitated carious lesions (18). The prevalence of dental caries in the primary dentition of the 6-7-year-old children studied was 95.6% when enamel and dentine carious lesions were considered, and 67.2% when solely dentine carious lesions were taken into account. The mean $d_2$mft and $d_3$mft scores were 6.9 and 3.2 respectively, while the mean D_2MFT score was 1.7 and the mean D_3MFT score 0.2. In the permanent dentition, a mean number of six teeth were examined. The decayed component for both caries indices was the predominant contributing factor and hardly any restoration or extraction was observed to have been conducted.

These results were slightly worse than those of the national epidemiological survey, (SB Brasil 2010) (4). The differences in findings between the Paranoá and the national surveys can be explained, in part, by a difference in age of the population (5-year-old children in SB Brasil and 6-7-year-old children in Paranoá), but also by the fact that the Paranoá Study was carried out in a deprived population, while the national survey encompassed all areas in Brazil, deprived or not. In addition to assessing the dental caries situation, the Paranoá Study investigated the clinical consequences of untreated cavitated dentine carious lesions using the pufa index (19). The prevalence of children with a pufa score was 23.7%. The p-component (pulpal involvement) was most prevalent (19.5%), followed by the f-component (fistulae) with 6.6%, the a-component (abscess) with 1.2%, and the u-component (ulceration) with 0.1%. The mean pufa score was 0.4 and toothache was reported by 20.1% of the children examined. The authors concluded that prevalence of consequences of untreated dentine carious lesions was moderate, while severity of dental caries was low.

It is worthwhile mentioning the difficulties encountered by the researchers involved in the epidemiological survey in reporting the data collected through the ICDAS II system. The disadvantages of using the system in epidemiology are discussed in detail by de Amorim et al. (18) and stimulated the research group into developing an alternative caries detection instrument to both the World Health Organization (WHO) criterion and ICDAS II system, called the Caries Assessment Spectrum and Treatment Instrument or 'CAST' (20,21).

The quality of life of the children and of their families was also assessed during the epidemiological survey. Results showed that quality of life was negatively influenced by the

presence of a pufa score, history of extraction and toothache. The presence of an untreated cavitated lesion without symptoms also affected quality of life, but to a much lower degree (8).

The results of the epidemiological survey clearly show that access to oral healthcare in Paranoá was not adequate and that the services provided (or the lack of them) were not fulfilling the needs of the population. It is most likely that the situation in Paranoá is no different from many other deprived communities in Brazil and that the outcomes of the Paranoá Study could bring oral healthcare benefits to all.

In Brazil, the main approach to managing cavitated carious lesions is the conventional one, based on restorative protocols that include rotary instruments and that require a fully equipped dental unit. As previously argued, this kind of oral healthcare is not accessible to the majority of children in deprived areas of the country. In the last two decades, the understanding that caries is preventable and should not be considered an infectious disease but a behavioural one with a bacterial component has strengthened the philosophy of Minimal Intervention Dentistry (MID), whose aim is summed up in the slogan: 'Teeth for Life'(22).

Based on the concept of MID and on the caries prevalence and caries experience, and number of untreated carious lesions in Paranoá's schoolchildren, three different oral healthcare protocols were introduced and compared. The study aimed to increase the understanding of how best to manage the existing cavitated dentine carious lesions in primary teeth and to prevent the development of new carious lesions in primary and, particularly, in high-caries-risk permanent molars. The protocols are described in brief below.

Conventional Restorative Treatment (CRT) – consists of restoring primary molars using rotary instruments and amalgam, and sealing high-caries-risk occlusal surfaces of first permanent molars (surface-level risk based on signs of lesion activity and depth of pits and fissures) using composite resin sealants.

Atraumatic Restorative Treatment (ART) – consists of restoring primary molars using a high-viscosity glass-ionomer cement (HVGIC) according to the ART approach, and sealing high-caries risk occlusal surfaces of first permanent molars with HVGIC ART sealants.

Ultra-conservative Treatment (UCT) – consists of restoring small non-cleansable cavities in primary teeth using ART and leaving medium- and large cavities open, and enlarging these when needed for allowing access for cleaning the cavity. The cleaning is performed with toothbrush and fluoridated toothpaste at school premises under daily supervision during

school hours. The high-caries-risk occlusal surfaces of first permanent molars are cleaned during this activity. No sealant is placed.

The CRT using amalgam as a restorative material was selected as the control group, as it is still one of the most common ways of treating primary molars in the public oral health centres in Brazil. The ART and the UCT were considered experimental groups. Both share the possibility of being implemented at school premises, in this way increasing accessibility. The UCT has a component (supervised tooth brushing) that does not require a dentist to perform. It was thought that application of UCT might have the added advantage of initiating a behavioural change in children/parents through removal/disruption of the biofilm with toothbrush and fluoride toothpaste. Whether the UCT is a viable protocol for treating cavitated dentine carious lesions in primary molars, for preventing carious lesions development in permanent molars and for improving oral hygiene standards in high-caries-risk children of a deprived community is one of the main topics of the Paranoá Study, and is in part the focus of the research presented in this thesis.

1.3 Oral healthcare protocols of the Paranoá Study: main findings of completed studies

The oral healthcare protocols were implemented from May to July 2009. While the treatments were being provided, the children's levels of anxiety and pain associated with the CRT, ART and UCT protocols were investigated. The results showed that children included in the study presented similar levels of anxiety and that pain reported after the three oral healthcare protocols was also similar. Nevertheless, local anaesthesia was significantly more often administered in children from the CRT group than in the ART and the UCT groups (23,24).

Another aspect that was investigated concerned whether the treatment provision had positively impacted on children and their families' quality of life. For that purpose, the results obtained through the Brazilian version of the Early Childhood Oral Health Impact Scale (B-ECOHIS), applied during the epidemiological survey and 1 year after the provision of treatments, were compared. The results did not show an overall improvement in quality of life, but all three protocols were able to reduce a child's felt pain (25).

Finally, primary molars of the UCT group, of which medium- and large cavities were not restored but kept open and cleaned under supervised tooth brushing, survived as long as those that had received amalgam or ART restorations (26). Moreover, no difference in the exfoliation patterns of the primary molars was observed when the three oral healthcare protocols were compared (27).

The present thesis deals with the survival of CRT and ART restorations in primary teeth over 3 years and with the caries-preventive effect of the two types of sealants in comparison with biofilm removal only in first permanent molars over 3 years. The final topic that is studied as part of the thesis relates to the change in level of biofilm and gingival bleeding present among the children in the oral healthcare protocols over a period of 4 years (Figure 1.1). The following sections describe the rationale for choosing the oral healthcare protocols.

1.4 Oral healthcare protocols for managing carious lesions in primary molars in schoolchildren

Cavitated dentine carious lesions in the primary dentition need to be arrested to maintain teeth in a healthy and functional state until natural exfoliation occurs. To avoid carious lesion progression, a surgical restorative approach, based on carious tissue excavation and insertion of a restorative material into the cavity, has been used for many decades. Traditionally, carious lesions are accessed, shaped to (pre-) established cavity designs and the carious tissue is excavated using rotary instruments. A restorative material, such as amalgam (still used in Brazil) or composite resin, is inserted into the cavity and sculpted to simulate the original tooth anatomy. This procedure demands a dental unit, electricity, running water and local anaesthesia.

An alternative to the conventional way of restoring teeth was developed in the eighties and nineties as a response to the lack of restorative care in deprived communities of Tanzania as rotary dental equipment turned out to be inappropriate (28). The so-called 'Atraumatic Restorative Treatment' (ART) uses hand instruments to access the cavity and for removal of soft carious tissue. Restoration is performed with an adhesive restorative material, usually an HVGIC that is pushed with finger pressure into the cavity and adjacent fissures (29). By not requiring rotary instruments, electricity or running water, the ART approach can be used virtually

anywhere. It causes less anxiety and pain than conventional treatment (30,31) while administering local anaesthetic is hardly required.

A systematic review of studies that compared the longevity of conventional amalgam and HVGIC ART restorations found no significant difference between treatment approaches (32). Owing to the limited number of studies and to issues that may compromise internal validity, the authors state that this result should be treated with caution and more controlled trials are needed to confirm the outcome.

Another systematic review, related to the survival of occlusoproximal restorations in primary teeth, included not only amalgam but also composite resin restorations in comparison with HVGIC ART restorations (33). The authors concluded that there was no significant difference between ART and composite resin or amalgam in occlusoproximal restorations in primary teeth. They also state that further controlled clinical investigations on the topic are necessary.

Since the signing of the Minamata Convention Agreement, a treaty of the United Nations Environmental Programme (UNEP), the use of amalgam is being phased-down in many countries (34). In response to this treaty, both the World Dental Federation (FDI) (35) and the WHO (36) have called for more emphasis to be placed on carious lesion prevention, on preventing placing restorations and on developing alternatives to amalgam.

HVGICs have successfully been used with the ART approach (37). However, low fracture toughness has always been a weak feature of glass-ionomers. In an attempt to circumvent this weakness, a new HVGIC was developed that contained a higher-than-usual powder-to-liquid ratio. This HVGIC was reported to have increased fracture toughness levels and was launched a decade ago (38). A decision was made to use this new HVGIC despite the unavailability of published clinical trials on the effectiveness of this improved HVGIC at the time that the Paranoá Study was planned. So, one question that this PhD thesis seeks to answer is: can HVGIC ART restorations, using the newly launched HVGIC, be considered a successor to amalgam restorations in primary teeth?

Despite the many improvements in dental materials and application techniques, restorations still tend to become defective with time (39). Usually, defective restorations are indicated for repair or replacement. But as primary teeth have a short lifespan and eventually exfoliate, it is opportune to pose the question: is it always necessary to replace/repair a defective restoration in a primary tooth? If the child is not harmed and not hindered from using

his/her dentitions, guiding a defectively restored primary tooth to exfoliation would be less costly and would permit the dentist to allocate time and energy to dealing with serious dental matters in other children.

Whether or not to re-restore defectively restored primary teeth has not been studied much. Boon et al. (40) observed that in many defective restorations the re-exposed dentine was hard and dark in colour and free of soft dentine 2 years after restoration breakdown. Lo and Holmgren (41) did not find caries progression in most of the defective ART restorations. They suggest that further research should develop a minimal but effective treatment approach for such primary teeth. However, before this suggestion is discussed, it is important to know if defective restored primary teeth left unrestored develop pain and sepsis over time. Therefore, this thesis investigates the survival of restored primary molars with intact and with defective restorations.

The question of whether it is necessary to re-restore defective restorations in primary teeth is in line with the view of an influential cariologist, who suggests that primary teeth may not always need to be restored (42). The logic for this suggestion is the fact that dental caries is considered a preventable disease, associated with the presence of cariogenic biofilm on tooth surfaces. More cariologists hold the view that a tooth cavity is restored because a restored tooth allows the removal of biofilm from tooth surfaces easily compared to biofilm that sits, for example, in a small cavity. In such a situation the chance that a cavity will progress is high and a restoration is required. But if the cavity were larger in size and accessible to toothbrush and fluoridated toothpaste, would it be possible to brush the cavity biofilm-free and stop the demineralisation of dentine within the cavity? This research question has already been answered for primary teeth as part of the Paranoá Study (26). It is the basis for the UCT protocol.

1.5 Oral healthcare protocols for preventing carious lesions in permanent molars in schoolchildren

Dental caries is a site-specific disease that in the permanent dentition occurs initially in pits and fissures of recently erupted molars (43,44). As the caries process is driven by the presence of a cariogenic biofilm, the most obvious measure for preventing new lesions development and

promoting the arrestment of existing lesions is regular mechanical removal or disruption of the biofilm (45). However, erupting teeth are difficult to clean and cleaning may be avoided because of tender gums and behavioural factors (46). This might lead to occlusal surfaces of erupting molars becoming covered by biofilm that remains in place for long periods of time (43). Fissures in occlusal surfaces, especially in those of permanent molars, form an almost perfect niche for biofilm stagnation (47). One way to alter this biofilm retention site is to fill pits and fissures with a dental material that has adhesive properties, resulting in a smooth surface that allows easy biofilm removal (48). Sealants are indicated for use in patients with a high-caries risk, in pits and fissures that present signs of carious lesion activity and/or are deep. Placing these in low-caries-risk patients with low-caries risk at tooth surface level is considered over-treatment (48).

Glass-ionomer can be used as a sealant material and be applied according to the ART approach. The advantages of the ART approach over other ways of applying glass-ionomer sealant material are related to the use of an HVGIC that has higher values for the material's physical properties than low- or medium-viscosity glass-ionomers and the fact that the HVGIC is pressed into pits and fissures under finger pressure. Hand instruments are used for removing excess material and for adjusting the bite (48). Being more hydrophilic than composite resin sealants, HVGIC is the material of choice when sealing teeth that cannot be adequately isolated, as in erupting and recently erupted molars (47,48).

Composite resin sealants, which consist of low filler particles for ensuring easy flow into pits and fissures, have a higher retention rate than a mix of sealants that consist of low-, medium- and high-viscosity glass-ionomers (49). Despite the variable 'retention of sealants' is considered a surrogate endpoint in determining the effectiveness of a type of sealant in preventing caries, it appears to be no relationship between dentine carious lesion development and loss of sealant material (50). Nevertheless, some researchers suggest that composite resin sealants should be preferred as they are retained longer than the group of different glass-ionomer sealants (49,51).

Systematic reviews have reported no difference in dentine carious lesion development between resin composite and glass-ionomer sealants over time (52,53). These reviews have compared all types of composite resin and different types of glass-ionomer sealants. The ART sealant only uses HVGIC and only one study had been published that had investigated the effectiveness of composite resin and HVGIC ART sealants when the Paranoá Study was

designed. That study showed a significantly higher dentine carious lesion preventive effect of ART sealants compared to composite resin sealants over a period of 5 years (54). This remarkable finding needed confirmation. Therefore, composite resin sealants were added to the CRT protocol and ART sealants to the ART protocol. This PhD research reports about the dentine carious lesion preventive effect and level of retention of these two types of sealants.

Sealant retention is traditionally calculated using a three-point category: fully retained, partially retained and completely lost. In survival analyses, fully and partially retained sealants are combined and compared with completely lost sealants. This dichotomy considers a fully and only a very small part of the pits and fissure system coverage with sealant material as being equal. Clinically and in assessing caries risk, this dichotomy does not make sense. Chen et al. (55) suggested a change in calculating retention in occlusal surfaces that requires the surface to be divided into three equal parts (sections). This new criterion already fails a sealant when one section (third) of the sealed occlusal surface is re-exposed to the oral environment, since the absence of sealant material in just one section increases the risk that a carious lesion will develop or progress. Only one study has investigated this so called 'modified criterion'. This PhD research reports about the retention of sealants calculated according to both the traditional and the modified categorisation of failed sealants.

In line with the rationale for non-restorative treatment of medium- and large-sized dentine cavities in primary teeth, removing the biofilm from permanent teeth through tooth brushing and fluoride-containing toothpaste seems logical. A few studies have reported that supervised tooth brushing at schools reduces dental caries experience (56,57). If the child is able to clean his/her teeth effectively, then the need for more complex treatments is reduced and the urgent need for increasing access to oral healthcare in communities currently deprived of it also reduced. After all, empowering the public to take (oral) health into their own hands by changing bad behaviour into healthy behaviour is a joint responsibility of the (oral) health profession and the public.

Adopting good oral biofilm control at a young age may have great benefits throughout one's life (46,58,59). Therefore, cleaning permanent teeth with toothbrush and fluoride-containing toothpaste was included in the UCT protocol as a carious lesion preventive measure. For ethical reasons, the UCT biofilm-related actions were carried out under supervision during school hours. The supervision was not available for children that were treated according to the CRT and ART protocols. The question arises whether the daily

supervision would result in a lower level of biofilm on tooth surfaces and of gingivitis over time. This PhD research reports about the effect of supervised tooth brushing over a period of 4 years.

If supervised tooth brushing in school hours is indeed the main measure that prevents the development of carious lesions in pits and fissures of just erupting permanent teeth, why is it necessary to seal these pits and fissures? It appears that sealing these surfaces costs more in terms of materials, equipment and salary. With this question in mind, the ultimate goal of the Paranoá Study is to assess the cost effectiveness of the three oral healthcare protocols over a period of 3 years.

This PhD research contributes to this goal by reporting the outcomes of the comparison between sealing high-caries-risk occlusal surfaces in first permanent molars and cleaning these surfaces with toothbrush and fluoride-containing toothpaste under daily supervision during school hours.

1.6 Aims of the PhD research

The aims of this PhD research are:

- to compare cumulative survival rates of amalgam and ART restorations in primary molars over a 3-year period;
- to compare survival rates of primary molars with intact and with defective amalgam and ART restorations over a 2-year period;
- to compare the effectiveness of two types of sealants and supervised tooth brushing in preventing dentine carious lesion development in high- and low-caries-risk occlusal surfaces of first permanent molars over 3 years;
- to compare the cumulative survival rate of retained composite resin and a newly formulated high-viscosity glass-ionomer ART sealants in first permanent molars over a period of 3 years using two retention assessment criteria;
- to evaluate the effectiveness of supervised tooth brushing on levels of biofilm and gingival bleeding in permanent teeth in comparison to non-supervised tooth brushing over a period of 4 years.

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CHAPTER 2

IS HIGH-VISCOSITY GLASS-IONOMER-CEMENT A SUCCESSOR TO AMALGAM FOR TREATING PRIMARY MOLARS?

This chapter has been published as:

Hilgert LA, de Amorim RG, Leal SC, Mulder J, Creugers NHJ, Frencken JE. Is high-viscosity glass-ionomer-cement a successor to amalgam for treating primary molars? Dent Mater 2014; 30: 1172-1178.

Abstract

Objectives: To assess and compare the cumulative survival rate of amalgam and atraumatic restorative treatment (ART) restorations in primary molars over three years. *Methods*: 280 children aged 6-7 years old were enrolled in a cluster randomized controlled clinical trial using a parallel group design covering two treatment groups: conventional restorative treatment with amalgam (CRT) and Atraumatic Restorative Treatment (ART) using a high-viscosity glass-ionomer (HVGIC) Ketac Molar Easymix. Three paedodontists placed 750 restorations (364 amalgam and 386 ART in 126 and 154 children, respectively) which were evaluated at 0.5, 1, 2 and 3 years. The proportional hazard rate regression model with frailty correction, ANOVA and Wald tests, and the Jackknife procedure were applied in analysing the data. *Results*: The cumulative survival rates over 3 years for all, single- and multiple-surface CRT/amalgam restorations (72.6%, 93.4%, 64.7%, respectively) were no different from those of comparable ART/HVGIC restorations (66.8%; 90.1% and 56.4%, respectively) ($p=0.10$). Single-surface restorations had higher survival rates than multiple-surface restorations for the both treatment procedures ($p<0.0001$). A higher proportion of restorations failed because of mechanical reasons (94.8%) than of secondary caries (5.2%). No difference in reasons for restoration failures between all type of amalgam and ART/HVGIC restorations were observed ($p=0.24$). *Significance*: The high-viscosity glass-ionomer used in this study in conjunction with the ART is a viable option for restoring carious dentine lesions in single surfaces in vital primary molars.

2.1 Introduction

The importance of restoring cavitated primary teeth, as the most obvious treatment, is debatable since studies have shown that unrestored cavitated teeth exfoliate naturally, without causing pain or sepsis in the majority of cases (1-4). Nevertheless, as little evidence is available regarding the effectiveness of non-restoring treatment approaches for managing cavitated primary teeth, restoring them remains the best option in the foreseeable future.

However, which restorative material should be used is unclear, according to a Cochrane systematic review (5). Amalgam has been used for decades and is considered by many to be the best material for restoring primary molars (6,7). Its application requires tooth preparation with rotary instruments and dental equipment that may not be always affordable in many communities (8,9). In addition, a number of countries have banned amalgam in response to the treaty agreed by the United Nations Environmental Programme (UNEP) (10). Both the World Dental Association (FDI) and the World Health Organization (WHO) have called for alternatives to amalgam (11,12). One alternative is to use currently available glass-based materials. The most common of these is glass-ionomer cement. Its high-viscosity type has become the material of choice for the atraumatic restorative treatment (ART). This caries management approach, which uses hand instruments only and a high-viscosity glass-ionomer cement (HVGIC), is considered an alternative to conventional restorative treatments (13). ART does not require use of rotary instruments, dental equipment or electricity (14,15) and is therefore less painful than conventional restoration and causes less dental anxiety, particularly in children (16-18).

In terms of restoration survival, a systematic review concluded that ART/HVGIC and amalgam restorations of the same size, type of dentition, and follow-up period are equally successful. However, because of the limited number of suitable datasets for the analysis, authors suggested that further studies should be carried out to confirm the findings (19).

A weak feature of glass-ionomer is its fracture toughness. By increasing the powder-to-liquid ratio, the fracture toughness was increased (20). It was suggested that using an improved glass-ionomer with the ART might increase the survival of ART restorations, especially in multiple-surface cavities (21).

The aim of the present study was to compare the cumulative survival rates of amalgam and ART restorations using a high-viscosity glass-ionomer with a higher than usual powder-to-

liquid ratio in primary molars over a period of three years. The null hypothesis tested is that there is no difference between the cumulative survival rates of amalgam and ART restorations in primary molars over a 3-year period.

2.2 Materials and Methods

2.2.1 Sampling procedure

This cluster-randomized controlled clinical trial used a parallel group design and was carried out in all the available six public primary schools of Paranoá, a deprived suburban area of Brasilia, Brazil. From an oral health epidemiological survey of 6- and 7-year-old children, attending these schools, the sample of the present study was chosen (22). Inclusion criteria were: 1) good general health; 2) at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the ICDAS II index. The trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference number 081/2008) and was registered at the Dutch Trial Registration Centre (reference number 1699). Parents and/or caretakers were informed in writing about the investigation and treatments. Children whose parents or caretakers filled in and signed the consent forms were included in the study.

The main study consisted of three groups: Conventional Restorative Treatment (CRT) protocol, the ART protocol and the Ultra-Conservative Treatment (UCT) protocol group. The UCT protocol was to restore small non-cleansable cavities with ART and to clean medium- and large-sized cavities with toothbrush and toothpaste daily (4). The unit of sampling was the school. As two of the six schools were equipped with a dental unit, these schools were allocated to the CRT group. The remaining four schools were randomly allocated to the ART and UCT groups. The current article concerns a secondary analysis and only reports the outcomes of the comparison between CRT/amalgam and ART/HVGIC restorations, and is a follow-up of a previously published report (23).

2.2.2 Implementation

Restorations were performed by three trained and calibrated paedodontists, aided by trained dental assistants, from May to July 2009 on the school premises, using a portable bed and an operating light. Children received an oral hygiene kit containing a toothbrush, fluoridated

dentifrice, plaque-disclosing dentifrice, and dental floss. They were instructed on how to use each element of the kit and were encouraged to brush their teeth twice daily. In the UCT group a trained dental assistant supervised children every second school day during tooth brushing sessions.

Conventional restorative treatment (CRT) protocol. Dentine carious cavities in primary molars were prepared with rotary instruments and restored, using a high-copper non-gamma 2 spherical and lathe cut amalgam (Permite Regular set®; SDI, Melbourne, Australia). The floors of the cavity and walls were prepared according to modified Black's principles, but the 'extension for prevention' concept was not followed up. Demineralized dentine was removed with a slow speed round bur. The bite was checked with articulation paper and excess material was removed with a carver.

Atraumatic restorative treatment (ART) protocol. Dentine carious cavities in primary molars were accessed and cleaned with hand instruments only (ART Kit; Henry Schein®, Chicago, USA), conditioned for 10 seconds with a wet cotton wool pellet saturated with the GIC liquid (polyacrylic acid), washed for 5 seconds, dried for 5 seconds with dry cotton wool pellets, and restored, using a high-viscosity glass-ionomer (Ketac Molar Easymix®, 3M ESPE, Seefeld, Germany) mixed according to manufacturer's instructions. The glass-ionomer was inserted into the cavity, using an applier/carver instrument (ART Kit; Henry Schein®), overfilled and pressed down with a petroleum-jelly-coated finger. Bite-check was performed and the applier/carver instrument was used to remove excess material.

In each treatment group, isolation was obtained through use of cotton wool rolls, local anaesthesia was administered when children indicated pain or whenever the operator judged it necessary. A calcium hydroxide liner (Hydro C®, Dentsply, Petrópolis, Rio de Janeiro, Brazil) covered with a glass-ionomer liner (Vidrion F®, SS White, Rio de Janeiro, Brazil) was applied on deep cavities. A wooden wedge and steel matrix band (Injecta®, Diadema, São Paulo, Brazil) in a Tofflemire matrix retainer (Golgran®, São Paulo, Brazil) were used for restoring proximal cavities.

Table 2.1 ART restoration criteria used in the present study

Code	Criteria
0	Present, satisfactory
1	Present, slight deficiency at cavity margin of less than 0.5 mm *
2	Present, deficiency at cavity margin of 0.5 mm or more *
3	Present, fracture in restoration
4	Present, fracture in tooth
5	Present, overextension of approximal margin of 0.5 mm or more *
6	Not present, most or all of restoration missing
7	Not present, other restorative treatment performed
8	Not present, tooth is not present
9	Unable to diagnose

*Assessed using the 0.5 mm ball-end of CPITN probe

2.2.3 Evaluation

Two independent evaluators (dentists) assessed restorations according to the ART restoration criteria (Table 1), on the school premises after 6 months, 1, 2 and 3 years. Evaluators were trained and calibrated before each evaluation session by an experienced epidemiologist (JF). Secondary caries was defined as an obvious dentine carious cavity. Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe (Golgran®) and compressed air aided the evaluation. A total of 198 restorations, presenting 543 surfaces, were re-examined for reproducibility testing. The inter-evaluator kappa coefficient value for assessing restoration failure over the four evaluation times was 0.75. The percentage of agreement was 92.6%.

2.2.4 Statistical analysis

The sample size was based on a power calculation using an α of 0.05 and a 1-β of 0.8. On the basis of an expected increase in the survival rate of multiple-surface ART restorations after two years from 65%(24) to 70%; the survival rate of amalgam restorations of 80% (25); a 10% correction for dependency of restorations; and an estimated annual loss of children of 8%, the required sample size was 365 restorations for each treatment group.

Statistical analyses were performed by a biostatistician using SAS (version 9.2) software. Restorations coded 0 and 1 were considered to have survived, those coded 2 to 6 were considered failures and codes 7 to 9 were considered censored observations. Presence of a dentine carious cavity alongside the restoration (secondary caries) was considered a failure. The presence of secondary caries prevailed over a mechanical failure in the same restoration,

except for failure coded 6 (restoration not present, most or all of restoration missing), since a complete displacement of the restoration is very unlikely to be justified by the occurrence of secondary caries but would rather be due to the restorative material used.

The dependent variable was the survival rate of restorations. Independent variables were: type of restoration (amalgam, ART/HVGIC); type of surface (single-surface, multiple-surfaces); gender; operator (1-3). ANOVA and chi-square tests were used to test for differences between independent variables at baseline and for non-response. The Proportional Hazard Rate Regression Model (PHREG) (26) with frailty correction (27) was used to estimate cumulative survival rates of amalgam and ART/HVGIC restorations over the total survival period. The Wald test (chi-square) was used to test for differences in survival rates and for estimating effects of the independent variables. The Jackknife method (28) was applied to calculate standard errors for use in the comparison of survival rates among restorations at one time point. Statistical significance was set at α=0.05.

2.3 Results

2.3.1 Baseline

A CONSORT flow diagram showing the number of children and restorations at the four evaluations times is presented in Figure 2.1. The mean (± SD) age of the children was 6.8 (± 0.4) years. Mean number of cavities per child was 3.2 (± 2.0), ranging from 1 to 14. At baseline no effects of gender (p=0.91), mean dmft (p=0.78) and DMFT (p=0.67) scores, and type of surface (p=0.72) were observed. An age effect (p<0.001) between children treated with amalgam and ART/HVGIC restorations was observed. Children receiving amalgam restorations were on average 0.2 years younger. The mean dmft and mean DMFT scores for the 280 children treated with ART/HVGIC and amalgam restorations were 5.8 (± 2.9) and 0.2 (± 0.6), respectively. Non-response analyses revealed no effect for type of restoration (p=0.58), age (p=0.43), gender (p=0.68), type of surface (p=0.55), baseline mean dmft (p=0.94) and baseline mean DMFT (p=0.86) scores.

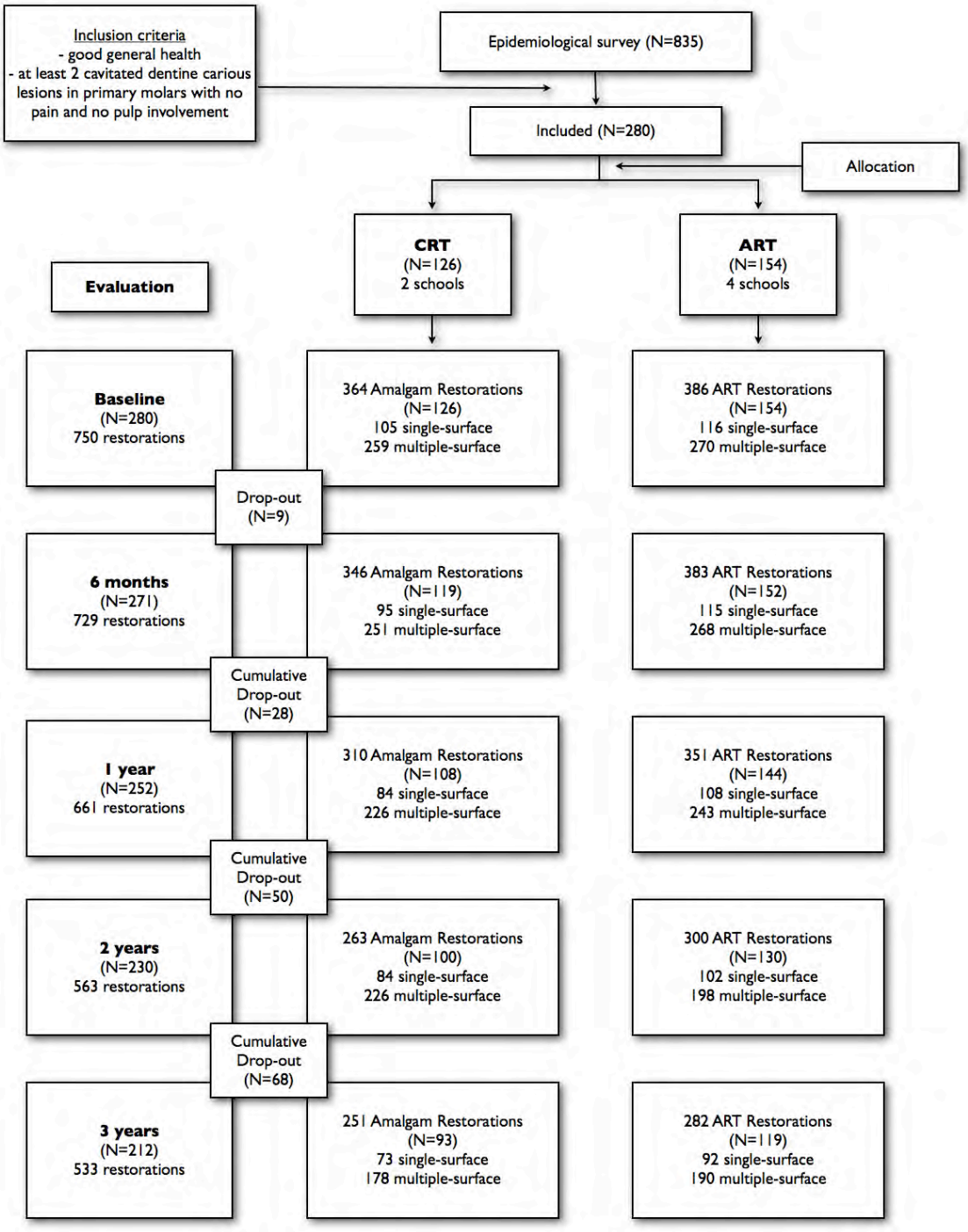

Figure 2.1 CONSORT flow diagram. N=Number of children

2.3.2 Handling of longitudinal data

Four evaluation times of 750 restorations corresponded to 3000 different sequences of evaluation scores, which were clearly interpretable (no errors, distinct moment of failure, or censored observation) or logically imputed (a missing observation was considered a success because the subsequent score was a success) in 99.2% of the cases. In 0.8% of the cases, the

distinct moment of failure could not be determined. It was decided to allocate these missing observations alternately to 'having survived' and 'having failed'.

2.3.3. Survival of restorations over 3 years

There was no statistically significant difference observed in the cumulative survival rate between ART/HVGIC restorations that had been cleaned under supervised tooth brushing during schooldays (UCT group) and those from the ART group (p=0.16). Therefore, the data regarding ART/HVGIC restorations of the main study's UCT and ART groups were combined in the analyses as the ART group of the present paper. Cumulative survival rates for single-surface, multiple-surfaces and all amalgam and ART/HVGIC restorations in primary molars for each evaluation time point are presented in Table 2.2.

The Proportional Hazard Rate Model showed an effect of the type of surface (p<0.0001), but no effects of gender (p=0.95), operator (p=0.12), and type of restoration (p=0.10), on the survival rates of restorations placed in primary molars over 3 years. The cumulative survival of single-surface restorations was higher than that of multiple-surface restorations for both treatment protocols (Table 2.2). No statistically significant differences were observed between cumulative survival rates of amalgam and ART/HVGIC restorations over the 3 years for all restorations (p=0.25), single-surface restorations (p=0.42) and multiple-surface restorations (p=0.19).

At the time point of 3 years, multiple-surface amalgam restorations had a statistically significantly higher survival rate (64.7%) than the ART multiple-surface restorations (56.4%) (p=0.03).

Mechanical failures accounted for 94.8% of all failed restorations examined, compared to 5.2% for secondary caries (Table 2.3). 'Most or all of restoration missing' was the most frequently scored fail condition for both amalgam and ART/HVGIC restorations. No statistically significant differences were found between all types of amalgam and ART/HVGIC restorations regarding reasons for mechanical failures and those due to secondary caries (p=0.24).

Table 2.2 Number of failures, cumulative survival rates (%) and SE, calculated by the Jackknife method, of amalgam and ART/HVGIC restorations placed in primary molars by interval

	All restorations						Single Surface						Multiple Surface					
	Amalgam			ART/HVGIC			Amalgam			ART/HVGIC			Amalgam			ART/HVGIC		
Interval	N_{fail}	%	SE	N_{fail}	%	SE	N_{fail}	%	SE	N_{fail}	%	SE	N_{fail}	%	SE	N_{fail}	%	SE
6 months	21	93.9	1.3	29	92.4	1.4	1	98.9	0.1	1	99.1	0.1	20	92.0	1.8	28	89.5	1.9
1 year	28	84.9	2.4	23	86.1	2.1	0	98.9	0.1	1	98.2	0.9	28	79.7	3.0	22	80.9	2.8
2 years	18	78.5	2.7	38	74.5	2.7	1	97.6[a]	1.1	5	93.4[b]	2.3	17	71.4	3.4	33	66.2	3.5
3 years	15	72.6	2.9	22	66.8	3.1	3	93.4	3.3	3	90.1	3.0	12	64.7[c]	3.6	19	56.4[d]	3.9

[a-b], p=0.02; [c-d], p=0.03.

Table 2.3 Number and distribution (%) of reasons for failure of amalgam and ART/HVGIC restorations by type of surface.

	Amalgam		ART/HVGIC		All failures
	Single Surface	Multiple Surface	Single Surface	Multiple Surface	
Secondary caries	1 (20%)	2 (2.6%)	2 (20%)	5(4.9%)	
	3 (3.7%)		7 (6.3%)		10 (5.2%)
Marginal deficiency ≥ 0.5mm (code 2)	0 (0%)	17 (22.1%)	1 (10%)	22 (21.6%)	40 (20.6%)
Fracture in restoration (code 3)	0 (0%)	3 (3.9%)	1 (10%)	1 (1.0%)	5 (2.6%)
Fracture in tooth (code 4)	2 (40%)	6 (7.8%)	0 (0%)	2 (2.0%)	10 (5.2%)
Most or all restoration is missing (code 6)	2 (40%)	49 (63.6%)	6 (60%)	72 (70.6%)	129 (66.5%)
ART restoration criteria	4 (80%)	75 (97.4%)	8 (80%)	97 (95.1%)	
(codes 2-6)	79 (96.3%)		105 (93.7%)		184 (94.8%)
All types of failures	5 (100%)	77 (100%)	10 (100%)	102 (100%)	
	82 (100%)		112 (100%)		194 (100%)

2.4. Discussion

2.4.1. Methodology

Allocation of children to the treatment groups was performed by cluster sampling of two schools, as two of the six schools had fully equipped dental units that could be used to perform the CRT protocol. However, those dental units had not been used for many years, as no dental personnel had been employed. Thus, children of the CRT schools had received no extra benefit in terms of oral health information and care than those of the other treatment groups. Although the socioeconomic status of the children was not assessed, schools were attended by children from an area of social and economical deprivation. Considering the findings that no effects of gender, mean dmft and mean DMFT scores, and type of surface were observed between children whose teeth had been restored according to the ART or CRT protocols, and that the children of the ART group were on average only 0.2 years older than children of the CRT group, the included children were comparable with respect to the most important studied aspects and therefore, selection bias was controlled.

When using distinguishable restorative materials such as amalgam and glass-ionomer, it is not possible to blind operators and evaluators regarding the treatment groups. The children may be considered as having been blinded, as the restorations were for the majority of them the first dental treatment that they had ever received. Assessment of restorations was performed by the same independent evaluators whose reliability scores over the 3 years were high. Therefore, even as operator and examiner blinding was not possible and this could have compromised the internal and external validity to a certain extent, the indication is that the collected data are reliable considering the nature of the study (29).

The present study applied the imputation method for handling of missing data between two evaluation scores. This procedure does not ignore possible differences between complete and incomplete cases which could compromise application of the analysis outcome to the population in all cases (30). Out of 3000 evaluation scores, 0.8% could not be reliably imputed. In a field trial like the present one, the outcomes appear to be a true reflection of the potential of the two treatments.

2.4.2 Main findings

No significant difference was found between cumulative survival rates of amalgam and ART restorations in primary teeth over 3 years. Therefore, the null hypothesis was not rejected. The finding is in line with that of systematic reviews regarding survival of amalgam and ART/HVGIC restorations in primary teeth (19,31).

As ART restorations do not require a dental clinic setting, the outcomes of the present study support the concept that through use of the ART approach more children of deprived areas will receive restorative care than they would through use of conventional approaches (32). Also, avoiding the use of rotary instruments appears to make the restorative experience less traumatic and to cause less discomfort (33).

It could be argued that, as in the present study restorations were performed under cotton wool roll isolation and not under rubber dam, saliva contamination could have influenced the outcomes. However, isolation with cotton wool rolls was shown to have the same effect as rubber dam on the survival rate of restorations (34,35). The 3-year survival rates of single- (90%) and multiple-surface (56%) ART/HVGIC restorations in the present study are higher than those reported for the same type of surfaces in the meta-analysis on ART procedures (66% and 31%, respectively) (21). Even though the increase in survival rates might be ascribed to the use of the high-viscosity glass-ionomer with a higher than usual powder-to-liquid ratio, those for multiple-surface ART/HVGIC restorations are not satisfactory. The amalgam restorations in the present study had a higher 3-year survival rate than those of a comparable study carried out a decade ago: single-surface (93% vs 80%) and multiple-surface restorations (65% vs. 43%) (36).

The statistical analysis, performed at the specific 3 years time point and not over the 3-year period as usual, revealed higher survival rates for amalgam multiple-surface restorations (64.7%) than for ART multiple-surface restorations (56.4%). The finding indicates that amalgam performed better than the improved glass-ionomer used in the present study after a longer time, and that further improvements are required before high-viscosity glass-ionomer, as for single-surface cavities, can be considered an alternative material to amalgam in multiple-surface cavities. However, it is debatable whether the difference in survival rate between the two types of material is an indication for re-restoring mechanically failed restorations at the age of 9-10 years, considering the short time that a primary molar tooth still has to remain and the high proportion of non-restored cavitated teeth that exfoliate without symptoms (3,37).

Since the start of the present study, further improvements in the composition and procedures of glass-ionomers have been made. In addition to strengthening the surface of glass-ionomers with a coat and to modifying its composition, which showed the encapsulated high-viscosity glass-ionomers to have significantly higher mechanical strength values than conventional high-viscosity glass-ionomers including the one used in the present study (38), applying heat from a high-intensity LED curing-light to the setting high-viscosity glass-ionomer seems to increased its fracture toughness (39). This aspect needs to be investigated in a clinical study and the outcome will determine whether a thermo-cured high-viscosity glass-ionomer can be considered a suitable alternative to amalgam in restoring multiple-surface cavities in primary teeth.

Secondary caries was the reason for failure of 5.2 percent of all restorations. This outcome is in line with a study conducted a decade earlier (36). The fact that no differences regarding reasons for failure between ART/HVGIC and amalgam restorations were observed, corroborates with the systematic review on this issue (40). Missing of (part) of the restoration was most common, particularly for multiple-surfaces restoration. The phenomenon might have been due to the low flexural strength of glass-ionomers, and to insufficient retention and/or inadequate thickness of amalgam.

The ART restoration criteria were used to evaluate restorations in the present study (Table 1). A total of 20.6 per cent of the failures were ascribed to a marginal defect of ≥ 0.5mm (code 2). It is noteworthy that the widely used Ryge criteria fail a restoration when the marginal defect exposes dentin (41). This implies that a number of failed restorations with code 2 would have been considered 'survived' if the Ryge criteria had been used in the present study. It would have results in higher survival rates for all types of restoration.

2.5 Conclusions

It is concluded that there was no significant differences regarding the cumulative survival rates of single-surface, multiple-surface and all amalgam and ART/HVGIC restorations in primary molars over the total period of 3 years. For both restorative materials, single-surface restorations survived longer than multiple-surface restorations. In the search for alternatives to amalgam, the high-viscosity glass-ionomer used in this study in conjunction with the ART

approach is a viable option for restoring carious dentine lesions in single surfaces in vital primary molars.

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CHAPTER 3

A STUDY ON THE SURVIVAL OF PRIMARY MOLARS WITH INTACT AND WITH DEFECTIVE RESTORATIONS

This chapter is a modification of the publication by Hilgert LA, Frencken JE, de Amorim RG, Mulder J, Leal SC. A study on the survival of primary molars with intact and with defective restorations. Int J Paediatr Dent 2015 (in press).

Abstract

Background: Failed restorations in primary teeth are not always re-restored. Is re-restoration not required anymore? *Objective*: To compare survival rates of primary molars with intact and defective amalgam and ART restorations. *Methods*: 649 restored primary molars, of which 162 were assessed with defective restorations for mechanical reasons, from a cluster-randomised controlled clinical trial, were followed over a period of 3.5 years. Restored primary molars, extracted because of dental sepsis or toothache, were considered a failure. Primary molars with defective restorations were followed from the time they were assessed defective. Data were analysed using PHREG model with frailty correction, Wald test, t-test and Jackknife procedure. *Results:* The survival rate of primary molars with intact restorations (97.5%) was statistically significantly higher than for those with defective restorations (75.9%) over a 2-year period ($P<0.0001$). After 3.5 years, 94.3% of primary molars with intact restorations survived. Neither the effect of restorative treatment (amalgam or ART)($P=0.05$) nor of type of surface (single or multiple)($P=0.73$) was observed with respect to the survival rate of restored primary molars. *Conclusions:* Survival rates for primary molars with intact and defective amalgam and ART restorations were high. The 2-year survival rate of primary molars with intact restorations was significantly higher than for those with defective restorations.

3.1 Introduction

Restoring cavitated dentine carious lesions with a plastic material is the most commonly used treatment for repairing affected teeth. This approach is particularly applicable for permanent teeth but presents a challenge for primary teeth (1,2). As removing cariogenic plaque from tooth surfaces regularly is considered one of the most important caries-preventive actions, removing it from within tooth cavities is expected to stop the progression of dental caries in these cavities. This assumption, together with the relatively short lifespan of a primary tooth, questions the necessity for always restoring a cavitated dentine carious lesion in a primary tooth (1). The age of the child and the level of cleanability are factors that determine the suitability of cleaning tooth cavities in primary teeth as a treatment option (3).

The effectiveness of cleaning medium to large tooth cavities in primary teeth and restoring small cavities with the Atraumatic Restorative Treatment (ART) approach has recently been reported (4). When this approach was compared to restoring all tooth cavities in primary teeth with rotary equipment and amalgam, and to restoring these with ART and high-viscosity glass-ionomer, the teeth survival of the three groups was found not to differ in children, initially aged 6 to 7, over a period of 3.5 years. The outcome supports the assumption that cleaning medium- to large-sized cavitated dentine carious lesions might be another option for treating tooth cavities, alongside restoring these carious lesions with a plastic material. This observation may guide the dentist in how defective restorations in primary teeth can be managed individually.

The approach that seems to be most commonly accepted within paediatric dentistry for managing defective restorations is to re-restore these. Replacing restorations generate substantial costs and usually increase the size of the cavity (5). Re-restoring may be wise if the child is young and the cavitated tooth still has a sizable number of years in which to perform. But one can argue that a different option is more suitable if the defective restoration in a primary tooth is present in a child of say 10 years of age. The remaining life of a tooth at that age is short and, depending on the type of failure, a re-exposed cavity could be kept clean using toothbrush and paste, just as has been described for medium- to large open cavities (4). Whether or not to re-restore a defective restoration in primary teeth has not been the focus of much research. Boon et al (6) observed a high percentage of re-exposed dentine being hard and dark in colour, and free of soft dentine 2 years after restoration breakdown in initially 6- to

8-year-old children. The authors concluded that it is not always necessary to re-restore defective restorations in primary teeth. However, they did not observe the natural course of these restored teeth and, therefore, were unable to determine whether a re-restoration was needed. Lo and Holmgren (7) also observed that teeth with defective restorations usually presented no caries progression and suggested further research to develop a minimal but effective treatment approach for such primary teeth.

As part of an investigation into the longevity of amalgam and ART restorations in primary teeth (8), teeth with intact and those with defective restorations were followed up for 3.5 years. The current publication reports on a secondary analysis that aimed to compare the survival percentage of primary molars with intact and defective restorations over the study period.

3.2 Materials and methods

3.2.1 Study design

The study reported on here was part of a cluster-randomised controlled clinical trial with a parallel group design (4) that was carried out in all six available public primary schools of Paranoá, a deprived suburban area of Brasília, Brazil, where the water system is artificially fluoridated (0.8 mg/l). The trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference number 081/2008) and was registered at The Netherlands Trial Register (reference number 1699). Parents and/or carers, after being informed in writing about the investigation and treatment protocols, filled in and signed the consent forms.

The main study consisted of three protocols for treating primary molars with cavitated dentine carious lesions in high caries-risk children, aged 6-7. Inclusion criteria were: 1) good general health and 2) at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the ICDAS II index. Treatment groups were: Conventional Restorative Treatment (CRT) protocol, the ART protocol and the Ultra-Conservative Treatment (UCT) protocol group. The UCT protocol was used to restore small non-cleanable cavities with ART and to clean medium- and large-sized cavities with toothbrush and fluoridated (1000 ppm) toothpaste (Contente; Suavetex Ltda, Uberlândia, Brazil) under supervision daily. The unit of sampling was the school. As two of the six schools were equipped with a dental unit (despite

the fact that no dentist had been employed at the schools for many years), they were allocated to the CRT group. The remaining four schools were randomly allocated to the ART and UCT groups.

3.2.2 Implementation

The implementation of the study has been described in details elsewhere (8). In summary, restorations were performed by three paedodontists, aided by dental assistants, from May to July 2009 at the school premises. Children received an oral hygiene kit containing a toothbrush, fluoridated toothpaste, plaque-disclosing dentifrice and dental floss, and were instructed on how to use these devices at school and at home.

Conventional restorative treatment (CRT) protocol. Dentine carious cavities in primary molars were prepared with rotary instruments. The floor and walls of the cavity were prepared according to Black's principles, but without the 'extension for prevention' concept. Demineralised dentine was removed with a slow-speed rounded bur. The restoration material was a high-copper non-gamma 2 spherical and lathe cut amalgam (Permite Regular set®; SDI, Melbourne, Australia). Bite was checked with articulation paper and excess material removed with a Hollemback carver.

Atraumatic restorative treatment (ART) protocol. Dentine carious cavities in primary molars were accessed and cleaned with hand instruments only (ART Kit; Henry Schein®, Chicago, USA), conditioned for 10 seconds with a wet cotton wool pellet saturated with GIC liquid (polyacrylic acid), washed for 5 seconds, dried for 5 seconds with dry cotton wool pellets and restored using a high-viscosity glass-ionomer (Ketac Molar Easymix®, 3M ESPE, Seefeld, Germany) mixed according to the manufacturer's instructions. The glass-ionomer was inserted into the cavity using an applier/carver instrument, overfilled and pressed down with a petroleum-jelly-coated finger. Bite-check was performed and the applier/carver instrument was used to remove excess material. Petroleum jelly was then placed over the restoration surface.

In each treatment group, isolation was obtained using cotton wool rolls. Local anaesthesia was administered when children indicated pain or whenever the operator judged it necessary. A calcium hydroxide liner (Hydro C®, Dentsply, Petrópolis, Rio de Janeiro, Brazil) covered with a glass-ionomer liner (Vidrion F®, SS White, Rio de Janeiro, Brazil) was applied to deep cavities. A wooden wedge and steel matrix band (Injecta®, Diadema, São Paulo, Brazil) in

a Tofflemire matrix retainer (Golgran®, São Caetano do Sul, Brazil) were used for restoring proximal cavities.

3.2.3 Evaluation

Two independent evaluators (dentists), who were trained and calibrated by a senior epidemiologist, assessed restorations according to the ART restoration criteria (Table 3.1), on the school premises after 0.5, 1, 2, 3 and 3.5 years. Restorations coded 0 and 1 were considered intact. Those coded 2 to 6 were considered defective as were those with a secondary carious lesion. Codes 7 to 9 were considered censored observations. Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe (Golgran®, São Caetano do Sul, Brazil) and compressed air aided the evaluation. The kappa coefficient value for the inter-evaluator consistency test over the evaluation period was 0.75. The percentage of agreement was 92.6%.

The two evaluators also assessed the presence or absence of (restored) teeth and whether or not such a tooth was painful and contained an abscess or fistulae. Children were asked whether (restored) teeth had exfoliated naturally or had been extracted during the previous evaluation interval. Painful teeth observed during evaluation were extracted by an operator who, during the evaluation interval, was called by phone either by the family or teacher in case the child had developed a painful tooth, and performed the treatment.

Table 3.1 ART restoration evaluation criteria used in the original study

Code	Criteria
0	Present, satisfactory
1	Present, slight deficiency at cavity margin of less than 0.5 mm *
2	Present, deficiency at cavity margin of 0.5 mm or more *
3	Present, fracture in restoration
4	Present, fracture in tooth
5	Present, overextension of approximal margin of 0.5 mm or more *
6	Not present, most or all of restoration missing
7	Not present, other restorative treatment performed
8	Not present, tooth is not present
9	Unable to diagnose

*Assessed using the 0.5 mm ball-end of CPITN probe

3.2.4 Statistical analysis

Statistical analyses were performed by a biostatistician using SAS version 9.2-software (Cary, IL, USA). The dependent variable was the survival of restored primary molars. A restored primary molar that had been extracted due to pain or to sepsis was considered a failure. The ART treatment protocol was composed of ART restorations from the ART group and those from the UCT group. Independent variables were: state of restoration (intact, defective); treatment protocol (CRT, ART) and type of tooth surface (single, multiple). Only restored teeth that were assessed at 0.5 year were followed, as that was the first time that restorations had been evaluated. This resulted in a database that covered 3 years for teeth with a defective restoration and 3.5 years for teeth with an intact restoration. In case a restoration was observed defective, the molar was considered censored for the group intact restoration, as tooth survival for a molar with an intact restoration cannot be observed anymore. If a restoration was assessed defective for mechanical reasons, that molar was transferred to the group defective restoration. As the outcome constitutes the start of the observation of a defective restoration over time, the starting time was reset for that restoration. The Proportional Hazard Rate Regression (PHREG) model (9) with frailty correction (10) was used to estimate survival rates of restored primary molars to test the independent variables. Teeth that had exfoliated and those that had been extracted by a non-study dentist were considered censored. The Wald test (chi-square) was used to test for differences in survival rates and for estimating effects of the independent variables. The Jackknife method (11) was applied to calculate standard errors for the comparison of survival rates at one time interval using a t-test. Statistical significance was set at $\alpha = 0.05$.

3.3 Results

3.3.1 Disposition of subjects

The total number of teeth with a restoration included in this secondary analysis was 681. During the 3.5-year observation period a total of 32 restorations were excluded from the analyses because they had failed and had been re-restored by the research team (N=22) and because the restoration had failed for reason of presence of secondary caries instead of a

mechanical reason (N=10). Of the available 649 teeth with a restoration included in the analyses, a total of 162 restorations were assessed defective during the 3.5-year period.

The number of primary molars with intact and defective restorations by treatment protocol and type of tooth surface over the 3.5-year observation period is presented in Table 3.2.

3.3.2 Effect of independent variables

PHREG application resulted in a statistically significant effect observed of the state of the restoration ($P < 0.0001$) but not of the type of surface ($P = 0.73$) and treatment protocol ($P = 0.05$) over the 3-year period.

Most teeth with defective restorations that had been extracted had an evaluation code 6 (11 out of 16) and concerned predominantly multiple-surfaces restorations (14 out of 16). For intact restorations that had been extracted, multiple-surfaces restorations predominated (12 out of 17) over single-surface restorations. Figure 3.1 shows representative cases of primary molars with defective restorations that had exfoliated naturally.

Table 3.2 The number of primary molars with intact and defective restorations by treatment protocol and type of tooth surface over the 3.5-year observation period

	Intact		Defective		Total
Treatment protocol Type of tooth surface	CRT	ART	CRT	ART	
Single	78	97	5	9	189
Multiple	161	151	71	77	460
Total	239	248	76	86	649

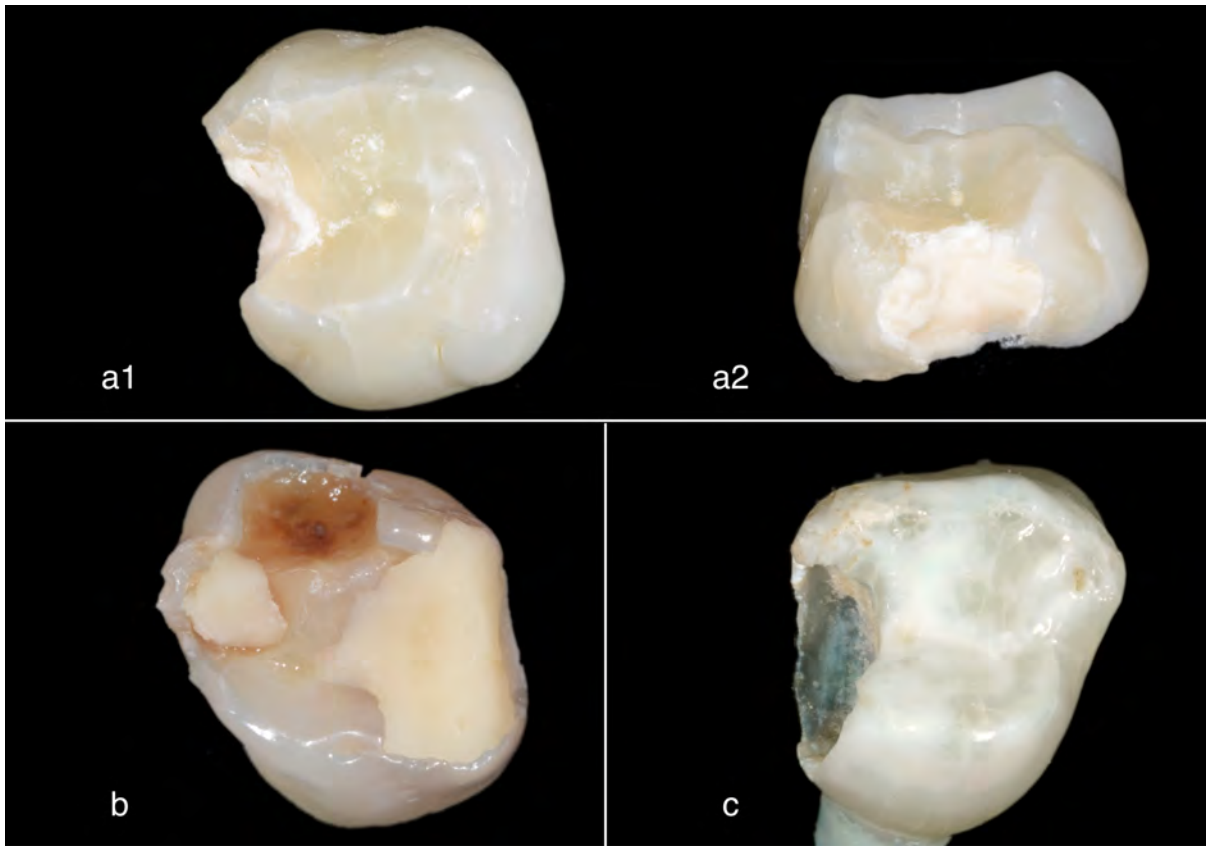

Figure 3.1 Representative images of three teeth with defective restorations that exfoliated naturally: (a1), (a2) and (b) show defective ART restorations; (c) presents a defective amalgam restoration.

3.3.3 Survival of restored primary molars

Estimating survival of restored primary molars with intact restorations started at time of placement, while that of teeth with defective restorations started at the moment a restoration was scored to have a mechanical defect. Table 3.3 shows the survival of restored primary molars with intact and defective restorations over the 3.5-years period. Time interval shows the length of time a restored primary molar was followed until tooth failure (extraction). For the observation period of two years, 75.9% of defectively restored primary molars survived in that condition, while 97.5% of restored primary molars, assessed as intact, survived two years ($P < 0.0001$). After 3.5 years, 94.3% of primary molars with intact restorations survived.

Table 3.3 Survival percentage (%) and Standard error (SE) of primary molars with intact and defective restorations over the 3.5-years period.

	Restored primary molars							
	Intact				Defective			
Time interval (yrs)*	N_{Entry}	Survived	SE	N_{Fail}	N_{Entry}	Survived	SE	N_{Fail}
0.0	649				162			
0.5					162	96.9	1.4	5
1.0	533	99.3	0.4	4	74	89.1	3.3	6
1.5					49	81.8	4.6	4
2.0	397	97.5	0.8	7	14	75.9	7.1	1
2.5					9			0
3.0	235	96.3	1.1	3	1			
3.5	144	94.3	1.7	3				

*Time starts at the beginning of the observation. For intact restoration it refers to the start of the study, for defective restorations it begins at the moment in which a mechanical failure of the restoration was identified. N_{Entry}= number of teeth evaluated at start of interval, N_{Fail}= number of teeth that failed (extracted because of toothache or sepsis) during the interval.

3.4 Discussion

3.4.1 Methodology

A detailed discussion on the methodology of the study from which this secondary analysis was drawn is presented elsewhere (8). Some brief comments on the methodology are provided below.

Allocation of children was performed by cluster sampling of two schools. Two of the schools had fully equipped dental units that had not been in use for many years as no dentists had been employed. Those units were reactivated and the schools allocated to the CRT protocol group. The remaining schools, in which no dental unit was required for performing the treatments, were allocated randomly to the ART and UCT groups. The authors have no reasons

to think that this form of allocation could interfere with the study's outcomes, since no effects of gender, mean dmft, mean DMFT and type of surface were observed among groups at baseline. Blinding of operators and evaluators is not possible to achieve in clinical studies that use distinguishable materials, such as amalgam and glass-ionomer. Children may be considered blinded as, for most of them, the restorations of the study were the first dental treatment they had ever received. Reliability of examiners was high and the same independent evaluators assessed the restored teeth throughout the study. Therefore, selection bias was considered controlled and methodological difficulties are thought not to have compromised the internal validity of the clinical trial seriously.

Most analyses regarding restoration survival in primary teeth focus on the quality of the restoration rather than the survival of the restored tooth. As the aim of restoring cavitated primary teeth is to keep these pain and sepsis free, and functioning until the moment they exfoliate, it seems logical also to obtain information about the natural course of mechanically defective restorations (6,7,12). As pain and sepsis might be expected in teeth with a secondary carious lesion, such defectively restored teeth had been excluded from the analyses, since new restorations are recommended to stop carious lesion progression. To ensure a pain and sepsis-free primary dentition, the research team stayed engaged with the school authorities and parents, performing any required oral care during the whole evaluation period.

As the survival analysis for primary molars with defective restorations could only start at the 0.5 years evaluation interval, the length of the survival was 3 years. During this period, 71.5% of the sample at 0.5 year was evaluated, which is considered substantial.

3.4.2 Main findings

Survival rates over 2 years were significantly lower for restored primary molars that presented defective restorations than for those that had intact restorations. Approximately 24% of primary molars with a history of restoration failure were extracted due to pain or sepsis while only 2.5% of those with intact restorations required extraction. As the present study appears to be the first one to report on such outcomes, comparison with other studies is not possible. Nevertheless, the 75.9% survival of teeth with a defective restoration over the 2-year period is considered high, particularly as 'most or all of restoration missing' was the main reason (67%) for scoring a restoration as defective in the main study (8). This finding was also observed in restoration trials in primary dentitions that had used the same evaluation criteria (7,12,13). The

outcome might have been influenced by the size of the cavities at baseline as the majority of the defective restorations were multiple-surface restorations. Such surfaces are relatively easier to clean than small-size cavities. This observation has been reported as a possible reason for the absence of lesion progression in primary teeth with defective restorations (7). Other reasons for the high survival rate of teeth with defective restoration in the present study might include: removal of cariogenic plaque and soft dentine during cavity cleaning, making self-cleaning easier (7); hypermineralisation of dentine from the glass-ionomer material used to restore the cavities (7); increased hardness of the dentine at the floor and walls of the cavity over time, which might facilitate plaque removal (6); and possibly the action of fluoride in dentifrice and drinking water in the study area, which might harden the re-exposed dentine.

As no other publication was found that had followed defective restoration longitudinally, it is of interest to discuss the findings of studies that have questioned the need to use the traditional restorative approach in treating cavitated dentine carious lesions in primary teeth. Levine et al (14) analysed the natural course of 1,587 teeth with unrestored dentine cavitated carious lesions and observed that 84% of those exfoliated with no symptoms. Tickle et al (15) reported that in a general practice context no difference was observed in the natural exfoliation without pain or sepsis between restored and unrestored decayed primary molars. Hu et al (2) prospectively followed up a population of 8-year-old children for 3.5 years and found that 81.5% of the teeth that presented cavitated dentine carious lesions and were left open (unrestored) exfoliated without symptoms. Mijan et al (4), studying the same population as presented in the present paper, observed no difference in teeth survival among primary molars that were treated by the CRT protocol using amalgam, the ART restorative protocol and the UCT protocol in which medium and large dentine cavities were left open and a school-based supervised tooth brushing programme was implemented. Over 3.5 years of follow up, 89% of the teeth from the UCT group survived, compared to 91% and 90% of the CRT and ART groups respectively.

When a decision not to restore a dentine cavity or not to replace or repair a defective restoration is taken, it is important to highlight that these kinds of 'ultraconservative' or 'non-operatory' oral care protocols are based on regular tooth brushing with fluoride toothpaste and education towards healthy oral habits with an emphasis on the cavitated dentine lesions. It must be emphasised that placing no restoration (and no re-restoration) is not the same as lack of management or supervised neglect (14). Sharing the responsibility of the treatment with the

parents and children by requiring better oral hygiene may improve treatment compliance and be more child-friendly than just restoring the cavities (1). Oral care protocols for children should always focus on involving the child and family in a behaviour-change process with possible life-long benefits.

Recommendation to re-restore or to repair a defective restoration in primary teeth should not solely reside at the evaluation of the restoration itself. It should include an analysis of the type of restorative failure to determine if the re-exposed cavity is easily cleaned or not. It is known that large multiple-surface restorations tend to present more defects than single-surface ones. This means that it could be advisable to shorten re-evaluation intervals for such treatments to enable identification of defective restorations earlier. Also, age, oral hygiene standards and access to fluoride sources of the patient should be considered. Younger patients have more difficulty in performing an adequate tooth brushing and have a longer expected permanence of primary teeth in function before exfoliation. Older children are able to promote better hygiene and their primary teeth exfoliate in a shorter time span. In deprived communities, continuous access to a toothbrush, fluoridated toothpaste and fluoridated water may be relevant. A universal clinical recommendation on when to 're-restore' a cavity is very unlikely to exist. It seems that developing criteria that help a sound judgement of each clinical case is much more important and could help in achieving an already fostered minimal but effective treatment approach for primary teeth (7).

Previous publications suggest that future studies should emphasise the analysis of teeth survival over restoration survival (6,12). The present study reinforces this recommendation. Also, future clinical trials should include a detailed protocol on what kind of treatment is to be given to a primary tooth that presents a defective restoration. The cost effectiveness of re-restoring or not is to be further researched.

In conclusion, survival rates for primary molars with defective and intact amalgam and ART restorations were high. The 2-year survival rate of primary molars with an intact restoration was significantly higher than that for primary molars with a defective restoration. When to re-restore defective restorations in primary teeth needs to become a topic of discussion.

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CHAPTER 4

CARIES-PREVENTIVE EFFECT OF SUPERVISED TOOTH BRUSHING AND SEALANTS

This chapter has been published as:

Hilgert LA, Leal SC, Mulder J, Creugers NHJ, Frencken JE. Caries-preventive effect of supervised tooth brushing and sealants. J Dent Res 2015;94:1218-24.

Abstract

Objective: To investigate the effectiveness of three caries-preventive measures on high- and low-caries risk occlusal surfaces of first permanent molars over 3 years. *Methods:* This cluster-randomized controlled clinical trial covered 242 schoolchildren, 6-7-years-old, from low socio-economic areas. At baseline, caries risk was assessed at tooth surface level, using a combination of ICDAS II and fissure depth codes. High-caries risk occlusal surfaces were treated according to daily supervised tooth brushing at school (STB), composite resin (CR) and high-viscosity glass-ionomer cement (ART-GIC) sealants. Low-caries risk occlusal surfaces received STB or no intervention. Evaluations were performed after 0.5, 1, 2 and 3 years. A cavitated dentine carious lesion was considered a failure. Data were analysed according to the Proportional Hazard Rate Regression model with frailty correction, Wald-test, ANOVA and t-test, using the Jackknife procedure for calculating standard errors. *Results:* The cumulative survival rates of cavitated dentine carious lesion-free high-caries risk occlusal surfaces were 95.6%, 91.4% and 90.2% for STB, CR and ART-GIC sealants, respectively over 3 years, which was not statistically significant different. For low-caries risk occlusal surfaces, no statistically significant difference was observed between the cumulative survival rate of STB (94.8%) and no-intervention (92.1%) groups over 3 years. *Conclusions:* There was neither a difference between supervised tooth brushing and CR and ART-GIC sealants on school premises in preventing cavitated dentine carious lesions in high-caries risk occlusal surfaces of first permanent molars nor between STB and no intervention for low-caries risk occlusal surfaces of first permanent molars over 3 years. Trial registration: The Netherlands National Trial Register, NTR1699

4.1 Introduction

The caries process is predominantly driven by the presence of a cariogenic biofilm. Its regular mechanical removal or disruption is an adequate measure for preventing carious lesion development and promoting its arrestment (1). However, good standards of oral care are not always achieved, as exemplified by the fact that among 291 diseases and injuries, untreated caries in permanent teeth was ranked the most prevalent disease (2).

Dental caries is a site-specific disease predominantly occurring in pits and fissures of occlusal surfaces (3,4). Sealing permanent molars is an effective method for preventing and controlling carious lesion development in pits and fissures (5). Resin and glass-ionomers are the materials predominantly used. Although resin-based sealants usually present higher retention rates (6), systematic reviews have reported no evidence of the caries-preventive superiority of either material (5,7-9). Placement of sealants, whether for preventive or therapeutic reasons, should be based on caries risk assessment (1) at patient and tooth surface level (10).

Preventing carious lesions in children rely for a large part on educating them in removing the biofilm regularly with toothbrush and fluoridated toothpaste (11,12). School-based supervised tooth brushing appears to reduce carious lesion progression (13,14). However, the question that remains unanswered is whether supervised tooth brushing at school is equally effective in preventing carious lesion development in occlusal surfaces of permanent teeth as is sealing these. This question is particularly relevant in disadvantaged populations that may have access to toothbrushes and toothpaste, but lack access to oral healthcare services.

The possibility of answering this question arose from a primary oral healthcare study conducted in primary schools in Brazil. In order to manage the prevention and progression of carious lesions in primary teeth, three treatment protocols were compared (15,16). As part of these protocols, the caries-preventive effect on permanent first molars of a supervised tooth brushing (STB) program, a composite resin (CR) and a high-viscosity glass-ionomer ART sealant (ART-GIC) were investigated.

The null hypotheses tested were: (1) there is no difference in the caries-preventive effects of supervised tooth brushing, CR and ART-GIC sealants on high-caries risk occlusal surfaces of first permanent molars over 3 years; (2) there is no difference between supervised tooth brushing and no intervention in their caries-preventive effects on low-caries risk occlusal surfaces of first permanent molars over 3 years.

4.2 Materials and Methods

4.2.1 Sampling procedure

This cluster-randomized controlled clinical trial used a parallel group design and was carried out in all the six public primary schools of Paranoá, a deprived suburban area of Brasilia which water system was artificially fluoridated. The sample was nested in an epidemiological survey of 6- and 7-year-olds attending these schools (17). The inclusion criteria for the main oral healthcare study were: 1) good general health; 2) at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the second digit of the ICDAS-II index; 3) erupted first permanent molars with the occlusal surface fully visible and accessible; 4) high-caries risk occlusal surfaces in first permanent molars, determined by ICDAS-II codes 2 and 3 or a combination of ICDAS-II code 1 and medium or deep fissures assessed according to Symons et al. (18); 5) having the consent form signed. Low-caries risk occlusal surfaces were determined by ICDAS-II codes 0 or 1 and shallow fissures.

The study covered three groups for treatment of high-caries risk occlusal surfaces. These were: supervised tooth brushing on school premises, CR sealants and ART-GIC sealants. The sampling unit was the school (two schools per cluster). As two of the six schools were equipped with a dental unit, these schools were allocated to the CR group. The remaining four schools were randomly allocated to the ART-GIC and the STB groups. All children were individually instructed by the dentist on how to brush their teeth at the start of the study and during the evaluation periods.

Low-caries risk occlusal surfaces of the first permanent molars of children in the CR and ART-GIC groups did not receive any special intervention. But the low-caries risk occlusal surfaces of the permanent teeth of children in the supervised tooth brushing group were brushed under supervision, as brushing only the high-caries risk occlusal surfaces was not possible. Therefore, for the low-caries risk occlusal surfaces there were two groups: supervised tooth brushing (STB) and no intervention (Figure 4.1). This implies that teeth from the STB group could belong to the high- or the low-caries risk group.

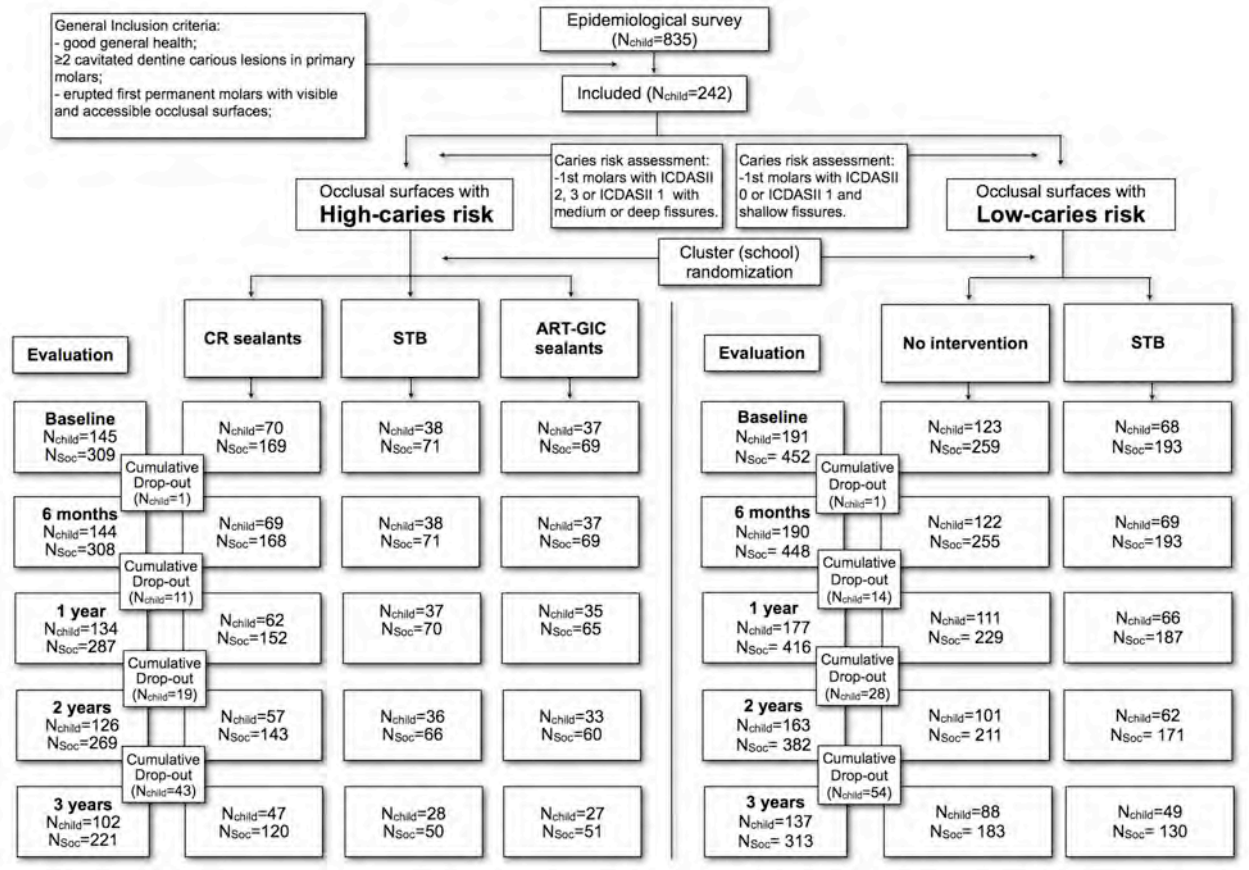

Figure 4.1 CONSORT flowchart (N_{child}=Number of children; N_{Soc}= Number of occlusal surfaces; CR=composite resin; ART-GIC= Atraumatic Restorative Treatment, high-viscosity glass-ionomer-cement; STB=supervised tooth brushing). Reasons for dropouts were: moving to another city and irregular school attendance.

The trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference 081/2008) and was registered at Netherlands Trial Register (reference 1699). Parents and/or carers were informed in writing about the investigation and treatments.

4.2.2 Implementation

Sealants were placed by three trained and calibrated paedodontists, aided by trained dental assistants between May-July 2009 on the school premises. Two experienced dentists performed training and calibration exercises. Tooth brushing was supervised from May 2009 to December 2012. All children received an oral hygiene kit containing toothbrush, a 1000ppm fluoridated dentifrice, plaque-disclosing dentifrice and dental floss. They were instructed how to use these devices and were encouraged to brush their teeth twice daily.

Composite resin sealant group (CR): Children were positioned in a dental chair. Isolation was performed with cotton wool rolls and a suction device. Using the operation lamp, occlusal surface was cleaned with a rotating brush, acid-etched for 30s with 37% phosphoric acid (Acigel, SSWhite, Rio de Janeiro, Brazil), rinsed and dried, using a 3-way syringe. The sealant material, Fluoroshield, (Dentsply, Petrópolis, Brazil) was placed in a dappen glass, transported to pits and fissures with a ball-ended probe (Duflex, Rio de Janeiro, Brazil) and light-cured for 40s (Ultralux, Dabi Atlante, Ribeirão Preto, Brazil). Occlusion was checked with carbon paper and adjusted when necessary with rotary instruments.

High-viscosity glass-ionomer sealant group (ART-GIC): Pits and fissures were cleaned with toothbrush and toothpaste before the children lay on the portable bed. Isolation was performed using cotton wool rolls. Plaque was further removed with a dental probe and cotton wool pellets under light provided by a portable headlamp. The occlusal surface was conditioned with polyacrylic acid for 10–15s, washed and dried with wet and dry cotton wool pellets, respectively. Ketac Molar Easymix, (3MESPE, Seefeld, Germany) was hand-mixed according to the manufacturer's instructions, applied on the occlusal surface with an ART applier instrument (Henry Schein, Chicago, USA) and pressed into pits and fissures by a petroleum-jelly coated finger for 15s (19). Excess material was removed with the ART carving instrument after bite registration with carbon paper. The sealant was coated with petroleum-jelly and children were told not to eat for 1 hour.

Supervised Tooth Brushing group (STB): Children were told to clean their teeth at least twice a day, and on every school day a dental assistant, trained in identifying plaque, supervised the tooth brushing sessions. Brushing instructions were repeated if needed. A conventional toothbrush and fluoridated toothpaste were used. Children were encouraged to maintain the same hygiene pattern at home and during school vacations.

4.2.3 Evaluation

Two independent evaluators (dentists) assessed teeth for the presence of carious lesions according to ICDAS-II on the school premises after 6 months and 1, 2 and 3 years. Evaluators were trained and calibrated before each evaluation session by an experienced dental epidemiologist (JF). Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe (Golgran®, São Caetano do Sul, Brazil) and compressed air aided the evaluation. A total of 210 sections were re-examined for reproducibility testing. The kappa-coefficient value for

the inter-evaluator consistency test in assessing carious lesions over the four evaluation times was 0.76. The percentage of agreement of scores was 86.7%.

4.2.4 Statistical analysis

The sample size of the present study relied on the power calculation of the main primary oral healthcare study. Focusing on the carious-lesion preventive effect of CR (79%) and ART-GIC (94%) sealants after 5 years (7), a power of 80%, a dropout rate of 30% and a correction for dependency of measurements of 20% gave a sample size of 117 sealants per group.

The statistical analyses were performed by a biostatistician using SAS version 9.2 software (Cary, NC, USA). The dependent variable was survival rate of cavitated dentine carious lesion-free occlusal surfaces. ICDAS-II codes 0-4 indicated survival, codes 5 and 6 failures and codes 96 and 99 censored observations. Treatment group (CR, STB, ART-GIC), age, gender and baseline caries experience (D_2MFT, D_3MFT and $d_3$mft) were the independent variables (D_2 represents ICDAS-II codes 1-6 and D_3/d_3 represents ICDAS-II codes 4-6). ANOVA and chi-square tests were used in testing for differences between the independent variables at baseline and for the non-response analysis. The Proportional Hazard Rate Regression model (PHREG) (20) with frailty correction (21) was used to estimate cumulative survival rates. The Wald-test (chi-square) was used to test for differences in survival rates and for estimating effects of the independent variables. The Jackknife method (22) was applied in calculating standard errors for comparing of survival rates between groups at one interval using t-test. Statistical significance was set at α =0.05.

4.3 Results

4.3.1 Disposition of subjects

A total of 242 children (126 boys, 116 girls) with a mean age of 6.8 (SD=0.4) years were enrolled in the study. At baseline, 761 first permanent molars were examined. The childrens' mean age, D_2MFT, D_3MFT and $d_3$mft counts, according to individuals having high-caries risk occlusal surfaces in first permanent molars, are presented in Table 4.1. A statistically significant difference at baseline between treatment groups was found for age and D_2MFT counts. Children of the STB group were approximately 3 months older than children who received CR

sealants and had lower mean D_2MFT counts. A CONSORT flow diagram is presented in Figure 4.1. After 3 years, overall dropout was 227 occlusal surfaces (29.8%).

4.3.2 Survival of Cavitated Dentine Carious Lesion-Free Occlusal Surfaces in First Permanent Molars

The numbers of cavitated dentine carious lesions in occlusal surfaces, cumulative survival rates and Standard Error (SE) according to the Jackknife procedure, for high-caries risk and low-caries risk occlusal surfaces in first permanent molars are presented in Tables 4.2 and 4.3, respectively. In high-caries risk and low-caries risk occlusal surfaces, 21 (6.8%) and 26 (5.8%), respectively developed a cavitated dentine carious lesion over the 3 years of follow-up.

The cumulative survival rates of cavitated dentine carious lesion-free occlusal surfaces of high-caries risk among the three treatment groups did not differ statistically significantly (p=0.59) (Table 4.2). There was no statistically significant difference (p=0.43) in cumulative survival rates of cavitated dentine carious lesion-free occlusal surfaces of low-risk between those that were brushed under supervision and those that received no intervention (Table 4.3).

Table 4.1 Mean (SD) of age, D_2MFT, D_3MFT and $d_3$mft counts of participating children with high caries risk occlusal surfaces at baseline according to treatment groups.

High-caries risk occlusal surfaces						
	CR sealants		STB		ART-GIC sealants	
	(N=70)		(N=38)		(N=37)	
	Mean	SD	Mean	SD	Mean	SD
Age	6.72	0.34	6.98	0.34	6.87	32
D_2MFT	3.37	1.02	2.53	1.22	3.00	1.13
D_3MFT	0.27	0.56	0.23	0.42	0.27	0.51
$d_3$mft	6.11	3.12	5.18	2.51	5.78	3.94
Age, p<0.01; D_2MFT, p<0.01; D_3MFT, p=0.36; $d_3$mft, p=0.26.						

N=Number of children; CR=composite resin; ART-GIC = Atraumatic Restorative Treatment, high-viscosity glass-ionomer-cement; STB=supervised tooth brushing

Table 4.2 Cumulative survival rates (%) and standard error (SE) of cavitated dentine carious lesion-free high-caries risk occlusal surfaces in first permanent molars over 3 years by treatment groups and interval

	CR sealants (N_{Soc}=169)			STB (N_{Soc}=71)			ART-GIC sealants (N_{Soc}=69)		
Interval (yrs)	N	%	SE	N	%	SE	N	%	SE
0.5	1	99.4	0.1	0	100.0	0.0	2	97.1	2.0
1	3	98.1	0.6	1	98.6	0.2	2	97.1	2.0
2	7	95.4	2.0	3	95.6	2.5	4	93.9	3.7
3	12	91.4	2.9	3	95.6	2.5	6	90.2	5.0

N_{Soc}=Number of occlusal surfaces at baseline; N=Number of cavitated dentine carious lesions; CR=composite resin; ART-GIC= Atraumatic Restorative Treatment, high-viscosity glass-ionomer-cement; STB=supervised tooth brushing

Table 4.3 Cumulative survival rates (%) and standard error (SE) of cavitated dentine carious lesion-free low-caries risk occlusal surfaces in first permanent molars over 3 years by treatment groups and interval

	No intervention (N_{Soc}=259)			STB (N_{Soc}=193)		
Interval (yrs)	N	%	SE	N	%	SE
0.5	3	98.8	0.7	4	97.9	1.0
1	9	96.2	1.4	4	97.9	1.0
2	10	95.8	1.4	7	96.2	1.6
3	17	92.1	2.1	9	94.8	1.6

N_{Soc}=Number of occlusal surfaces at baseline; N=Number of cavitated dentin carious lesions; STB=supervised tooth brushing

4.3.3 Analyses of Independent Variables and Non-Response

The PHREG model showed no effects of age (p=0.27), gender (p=0.85) and baseline $d_3$mft (p=0.15), D_2MFT (p=0.80), D_3MFT (p=0.09) counts on the survival rates of cavitated dentine carious lesion-free high-caries risk occlusal surfaces by treatment group. Non-response analysis revealed no effect for treatment group (p=0.72), age (p=0.90), gender (p=0.72), baseline $d_3$mft (p=0.38), D_2MFT (p=0.82) and D_3MFT (p=0.52) counts.

For the low-caries risk occlusal surfaces age (p=0.98), gender (p=0.32), baseline $d_3$mft (p=0.17), baseline D_2MFT (p=0.86) and baseline D_3MFT (p=0.86) counts had no effect on the

cumulative survival rates. Non-response analysis showed that there was no effect for supervised brushing (p=1.00), age (p=0.69), gender (p=0.75), baseline $d_3$mft (p=0.63), D_2MFT (p=0.42) and D_3MFT (p=0.62) counts.

4.3.4 Development of Cavitated Dentine Carious Lesions over 3 Years

The frequency distribution of components of the inclusion criteria and of cavitated dentine carious lesion development during 3 years is presented by occlusal surfaces' level of caries-risk assessment and treatment group in Table 4.4. At baseline, no statistically significant difference was observed in the distribution of components of the inclusion criteria by treatment group (high-caries risk, p=0.06; low-caries risk, p=0.58). For the high-caries risk occlusal surfaces, there was a higher percentage of ICDAS-II codes 2 and 3 that progressed into a cavitated dentin carious lesion than for code 1 (10.3% vs. 3.1%, p=0.02). Notably, in the STB group all six lesions that were scored code 3 at baseline did not progress into a cavitated dentine carious lesion.

Table 4.4 Frequency distribution (%) of components of the inclusion criteria and that of cavitated dentine carious lesion development in occlusal surfaces in first permanent molars over 3 years according to caries risk assessment and treatment groups

High-caries risk occlusal surfaces							Low-caries risk occlusal surfaces				
	CR sealants		STB		ART-GIC sealants			No intervention		STB	
Baseline ICDAS (Fissures)	N_{Soc} (%)	N_{DCav} (%)	N_{Soc} (%)	N_{DCav} (%)	N_{Soc} (%)	N_{DCav} (%)	Baseline ICDAS (Fissures)	N_{Soc} (%)	N_{Dcav} (%)	N_{Soc} (%)	N_{DCav} (%)
1 (F2)	67 (39.9)	3 (4.5)	38 (53.5)	1 (2.6)	42 (60.9)	2 (4.8)	0	183 (71.8)	13 (7.1)	143 (74.1)	3 (2.1)
1 (F3)	10 (6.0)	0 (0.0)	2 (2.8)	0 (0.0)	3 (4.3)	0 (0.0)	1 (F1)	72 (28.2)	4 (5.5)	50 (25.9)	6 (12)
2	65 (38.7)	4 (6.2)	25 (35.2)	2 (8.0)	15 (21.7)	2 (13.3)					
3	26 (15.5)	5 (19.2)	6 (8.5)	0 (0.0)	9 (13.0)	2 (22.2)					

N_{Soc}= Number of occlusal surfaces; N_{DCav}=number of cavitated dentine carious lesions; F1=shallow fissures; F2=medium fissures; F3=deep fissures; CR=composite resin; ART-GIC= Atraumatic Restorative Treatment, high-viscosity glass-ionomer-cement; STB=supervised tooth brushing; ICDAS= International Caries Detection and Assessment System

4.4 Discussion

4.4.1 Methodology

Allocation of children to the treatment groups was performed by cluster sampling because two of the six public primary schools in this low socio-economic area, had a fully equipped dental unit. However, children from these schools had no obvious advantage in terms of better oral health knowledge than children of the other four schools as no dentist had been employed for many years. Despite a significant difference observed in age and mean D_2MFT counts between the treatment groups at baseline, these variables had no effect on the survival rate of cavitated dentine carious lesions-free surfaces for high and low-caries risk occlusal surfaces of first permanent molars over the 3 years. Moreover, non-response analysis did not show a significant difference for any of the variables under study. All these findings support the assumption that bias in the composition of the treatment groups and in that of caries load in occlusal surfaces within the study groups was controlled.

A surface-level risk assessment was used for determining the risk category of erupted first permanent molars. Use of initial signs of carious lesions and fissure classification allowed for a more realistic comparison between treatments for occlusal surfaces than is usually possible if caries risk is determined at child-level only (10,23). Also the surface-level risk assessment grouped same stages of carious lesion development at baseline, avoiding comparison between surfaces that at the beginning had no signs of a carious lesion with those that already contained an enamel carious lesion, a situation often seen in sealant studies.

Children were blinded to the treatment they received, as only one type of treatment was provided per school. Operators could not be blinded, since the sealant application protocols were considerably different. Evaluators could not be blinded, as they could distinguish the sealant materials. During the later evaluations, when the sealant materials had disappeared from a sizable number of occlusal surfaces it was possible that evaluators examined the occlusal surfaces in a reasonably blind way. The statistician was blinded to the meaning of the group codes in the database. The dropout rates were considerable, despite the many efforts made to recall the children. Considering the above, the internal validity of the present study can be considered substantial for a trial of this nature (24). External validity is dependent on the experiences of the operators, dedication of supervising persons, participation of children and parents in brushing teeth during non-school days, and is therefore considered not very high.

4.4.2 Main Findings

The first null hypothesis was accepted. There is no difference in the caries-preventive effect of STB, CR and ART-GIC sealants on high-caries risk occlusal surfaces of first permanent molars over a period of 3 years. Evidence of the efficacy of sealants in preventing cavitated dentine carious lesions in high-caries risk children and adolescents, when compared to no sealants, is well established (5). The absence of a difference in survival rates of cavitated dentine carious lesion-free occlusal surfaces between the two sealant groups in the present study is in agreement with (5,7,9,25) but not with Beiruti et al. (26) that showed higher survival rates for ART-GIC than for CR sealants.

The efficacy of supervised tooth brushing in reducing development and promoting arrestment of enamel carious lesions has been described (13,14). Individualized non-operative intensive treatment based on patient education and professional tooth cleaning (Nexø model) has shown promising results in reducing operative treatment for occlusal surfaces of erupting first permanent molars (27). However, a direct comparison between different sealant materials and supervised tooth brushing in a high-caries risk population after a tooth-level assessment of high-caries risk occlusal surfaces in first permanent molars, as investigated in the present study, is new to the current knowledge of the authors.

The composite resin and the ART-GIC sealant used in the present study are both preventive measures that act as a diffusion barrier in areas that favour biofilm retention. By impeding biofilm accumulation in these areas, sealants are effective. Both sealants appear to release fluoride, although this might occur for a short period only as the migration of ions are stopped after the material has set fully. On the other hand, supervised tooth brushing acts by actively and repeatedly removing biofilm from the tooth surfaces supported by the fluoridated toothpaste. When the three protocols used for high-caries risk occlusal surfaces are compared it is possible to say that all protocols act by interfering in the accumulation of the biofilm and by the action of fluorides.

The finding that daily supervised tooth brushing is as good as sealants in preventing cavitated dentine carious lesions stimulates the discussion about the conditions under which sealants are really indicated and when supervised tooth brushing is a real option indeed. This discussion is of great importance in establishing guidelines for school-based preventive strategies for children at high-risk of developing occlusal carious lesions (3,4,28). While sealants

are surface-located treatments, educating children in applying oral hygiene daily through supervised tooth brushing might have a further-reaching impact through preventing carious lesions at any tooth in the mouth. Future studies should focus on the effects of supervised tooth brushing on the overall caries experience in children, plaque deposition, gingival bleeding and cost-effectiveness of this protocol in comparison to those of sealants.

An interesting finding was that all six ICDAS-II coded 3 lesions of the STB group in high-caries risk occlusal surfaces of first permanent molars did not progress to cavitation in dentine after 3 years. Although the number of such lesions was rather low, this finding may suggest that localized enamel lesions do not necessarily have to be treated with a sealant or even through an ultra-conservative restoration, as was suggested recently (29). The potential for arresting carious lesion progression solely with supervised tooth brushing, even in high-caries risk surfaces, is very important and the results of the present study should be confirmed by other research groups.

The second null hypothesis was accepted. There was no difference in caries-preventive effect between STB and no intervention for low-caries risk occlusal surfaces in first permanent molars over 3 years. The first permanent molars with initially sound occlusal surfaces and surfaces with initial stages of carious lesion development in combination with shallow fissures, did not benefit more from the STB than from no intervention.

The combined outcome of the two hypotheses is that tooth brushing under daily supervision at schools, covering some 200 days per year, resulted in a very low percentage of cavitated dentine carious lesions over 3 years. It is concluded that there was no difference in preventing cavitated dentine carious lesions in occlusal surfaces of high-caries risk permanent first molars between daily supervised tooth brushing and placing sealants on school premises over 3 years. For low-caries risk first permanent molars, supervised daily tooth brushing showed no difference with no intervention in preventing cavitated dentine carious lesions in occlusal surfaces over 3 years.

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CHAPTER 5

3-YEAR SURVIVAL RATES OF RETAINED COMPOSITE RESIN AND ART SEALANTS USING TWO ASSESSMENT CRITERIA

This chapter will be submitted for publication as:

Hilgert LA, Leal SC, Freire GML, Mulder J, Frencken JE. 3-Year survival rates of retained composite resin and ART sealants using two assessment criteria.

Abstract

Objectives: To test the null-hypothesis that there is no difference in the cumulative survival rate of retained composite resin (CR) sealants and a newly formulated high-viscosity glass-ionomer Atraumatic Restorative Treatment (ART) sealant in first permanent molars calculated according to the traditional and the modified retention assessment criteria over a period of 3 years. *Methods:* This cluster-randomized controlled clinical trial consisted of 123 schoolchildren, 6-7-years-old. At baseline, high-caries risk pits and fissures of fully erupted first permanent molars were treated with CR and ART sealants. Evaluations were performed after 0.5, 1, 2 and 3 years by two calibrated evaluators. Retention was scored for free-smooth surface and for each of the three sections into which the occlusal surface had been divided. The modified criterion differed from the traditional in that it determined an occlusal sealant to be a failure when at least one section contained no visible sealant material. Data were analysed according to the PHREG model with frailty correction, Wald-test, ANOVA and t-test, using the Jackknife procedure. *Results:* The cumulative survival rates for retained CR and ART sealants in free-smooth and occlusal surfaces for both criteria were not statistically significantly different over the total 3 years. A higher percentage of retained CR sealants on occlusal surfaces was observed at longer evaluations. Cumulative survival rates were statistically significantly lower for the modified criterion in comparison to the traditional one. *Significance:* Survival rates of retained CR and ART sealants decreased over time, with no significant difference between treatment groups. The modified retention assessment criterion should be used in future sealant-retention studies.

5.1 Introduction

Dental carious lesions predominantly occur in pits and fissures of occlusal surfaces in recently erupted molars (1,2). Placing sealants on occlusal surfaces of permanent molars is an effective method for preventing and controlling carious lesion development in pits and fissures (3). Currently, the main materials used for sealing pits and fissures are resin- and glass-ionomer-based (4,5). Retention of sealants is considered a surrogate endpoint for determining the caries-preventive effectiveness of sealants since it is believed that loss of retention would determine sealant failure. However, obtaining a real clinical endpoint by comparing sealed and non-sealed surfaces is difficult for ethical reasons, since the effectiveness of sealants for high-caries risk populations has already been established (5,6).

Resin-based sealants usually present higher retention rates than glass-ionomer (GIC) based sealants (6). Despite differences in their retention, systematic reviews have reported no evidence of caries-preventive superiority of either material (3,4,7,8). In the past, low- and medium-viscosity glass-ionomers were used as sealant material but these have been replaced by high-viscosity glass-ionomers, as the latter have increased mechanical properties, which have enhanced sealant retention (9). Retention of high-viscosity glass-ionomers may further be increased through the development of new formulas in the glass-ionomer technology, such as has been reported regarding its powder composition (10).

In calculating survival of sealants' retention, the traditional criterion considers a sealant a failure if all material has disappeared from the total sealed tooth surface. However, this criterion is questioned since absence of material in just a section of the occlusal surface re-exposes that section to the oral environment, which increases the chance that a new carious lesion is initiated or that an existing one progresses. This has led Chen et al (11) to suggest a new way of determining sealant retention. The so called: 'modified' retention criterion fails a sealant for its retention on the occlusal surface when only one section is re-exposed. Only a few studies have investigated the effect of the modified retention criterion on the carious lesion development and, consequently, for determining the need for resealing re-exposed pits and fissures.

In 2009, a cluster-randomized clinical trial was undertaken to compare the effectiveness of three treatment protocols among primary school going children (12). Investigating the

caries-preventive effect on permanent first molars of a supervised tooth brushing (STB) programme, a composite resin (CR) sealant and a newly formulated high-viscosity glass-ionomer sealant applied with finger pressure (Atraumatic Restorative Treatment or ART sealant) were part of the trial (13). The study provided the opportunity to test the following null-hypothesis: there is no difference in the cumulative survival rate of retained CR and newly formulated high-viscosity glass-ionomer cement ART sealants in permanent molars calculated according to the traditional and the modified retention assessment criteria over a period of 3 years. Furthermore, secondary analyses tested whether or not the level of sealant retention is related to the prevalence of cavitated dentine carious lesions over a period of 3 years.

5.2 Materials and methods

5.2.1 Sampling procedure

The cluster-randomized controlled clinical trial used a parallel group design. It was carried out in four public primary schools of Paranoá, a deprived suburban area of Brasilia, Brazil. The sample of this study was obtained from an oral health epidemiological survey among 6- and 7-year-old children attending all the schools in this area (14). The inclusion criteria were: 1) good general health; 2) at least two cavitated dentine carious lesions in vital pain-free primary molars assessed according to the ICDAS II index (15); 3) erupted first permanent molars with pits and fissures fully visible and accessible; 4) high-caries risk surfaces, determined by ICDAS II codes 2 and 3 or a combination of ICDAS II code 1 and medium or deep fissures assessed according to the Symons criteria (16); and 5) having a signed consent form (the sample of the present Chapter 5 consists of all first permanent molars that were sealed - on occlusal and buccal/lingual surfaces -, different from the 'sealants' part of the sample of Chapter 4 that dealt with occlusal surfaces only).

The study covered two groups to treat high-caries risk surfaces of first permanent molars. These were: CR sealants and ART sealants. The sampling unit was the school (two schools per cluster). Two of the four schools were equipped with a dental unit and were allocated to the CR sealants group. A CONSORT flowchart that depicts the study design is presented in Figure 5.1.

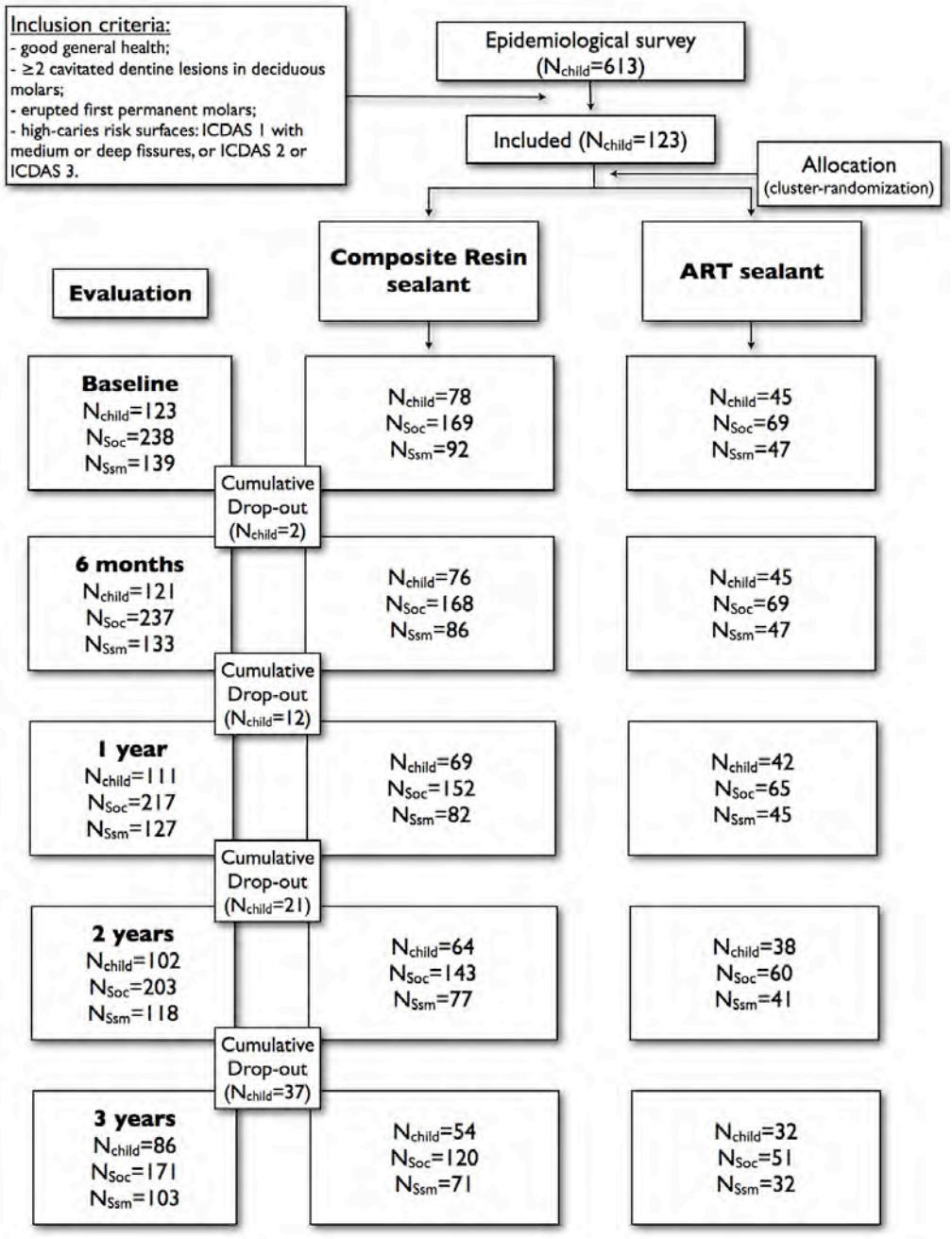

Figure 5.1 CONSORT flowchart (Nchild=Number of children; NSoc=Number of occlusal surfaces; NSsm=Number of smooth surfaces; ART=Atraumatic Restorative Treatment). Reasons for dropouts were: moving to another city and irregular school attendance.

The trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference number 081/2008) and was registered at The Netherlands Trial

Register (reference number 1699). Parents and/or carers were informed in writing about the investigation and were asked to sign a consent form that authorized their children to participate.

5.2.2 Implementation

Sealants were placed by three trained and calibrated paedodontists, aided by trained dental assistants, between May and July 2009 at the school premises. Children received an oral hygiene kit (toothbrush, fluoridated dentifrice, plaque-disclosing dentifrice and dental floss) and instructions on how to use its content at the start of the study. These instructions were repeated during the evaluation sessions. Children were encouraged to brush twice daily.

Composite resin sealant group (CR): Children were positioned in a dental chair. Isolation was obtained with cotton wool rolls and a suction device. Under good visibility from the operation lamp, the surface to be treated was cleaned with a rotating brush, acid-etched for 30 s with a 37% phosphoric acid gel (Acigel, SSWhite, Rio de Janeiro, Brazil), rinsed and dried, using a 3-way syringe. The sealant material, Fluoroshield, (Dentsply, Petrópolis, Brazil) was placed in a dappen glass, transported to pits and fissures with a ball-ended probe (Duflex, Rio de Janeiro, Brazil) and light-cured for 40 s (Ultralux, Dabi Atlante, Ribeirão Preto, Brazil). Occlusion was checked with carbon paper and adjusted where necessary with rotary instruments.

High-viscosity glass-ionomer ART sealant group (ART): Pits and fissures were cleaned with a toothbrush and toothpaste before the children lay on a portable bed. Isolation was obtained using cotton wool rolls. The occlusal surface was further cleaned with a dental probe and cotton wool pellets under artificial light provided by a portable headlamp. The surface was conditioned with polyacrylic acid for 10–15 s, washed with wet cotton wool pellets and dried with dry cotton wool pellets. Ketac Molar Easymix (3M ESPE, Seefeld, Germany) was hand-mixed according to the manufacturer's instructions, applied on the surface with an ART applier instrument (Henry Schein, Chicago, USA) and pressed into the pits and fissures with a petroleum jelly-coated finger for 15 s (17). Excess material was removed with the ART carving instrument after the occlusion was checked with carbon paper. The sealant was coated with petroleum jelly and the children were told not to eat for 1 hour.

5.2.3 Evaluation

For evaluating sealant retention and carious lesion development, the occlusal surfaces of the first permanent molars were divided into three sections (mesial-central-distal) (Figure 5.2) but the free-smooth surfaces were not. Each of these sections and free-smooth surfaces were assessed for the presence of carious lesions using ICDAS II. Retention was scored according to the codes: 0 (a sealant is present, good seal in the main pits and fissures initially sealed); 1 (partial loss of sealant that exposes the main pits and fissures); or 6 (no sealant is visible, main pits and fissures are completely exposed). The same two independent evaluators (dentists) performed the evaluations at the school premises after 6 months, 1, 2 and 3 years.

The evaluators were trained and calibrated before each evaluation session by an experienced dental epidemiologist (JF). Battery-illuminated dental mirrors (Kudos®, Hong Kong, China), CPITN probe (Golgran®, São Caetano do Sul, Brazil) and compressed air aided the evaluation. A total of 67 surfaces were re-examined for reproducibility testing. The kappa coefficient value for the inter-evaluator consistency test in assessing retention over the four evaluation times was 0.77 while the percentage of agreement was 86.6%.

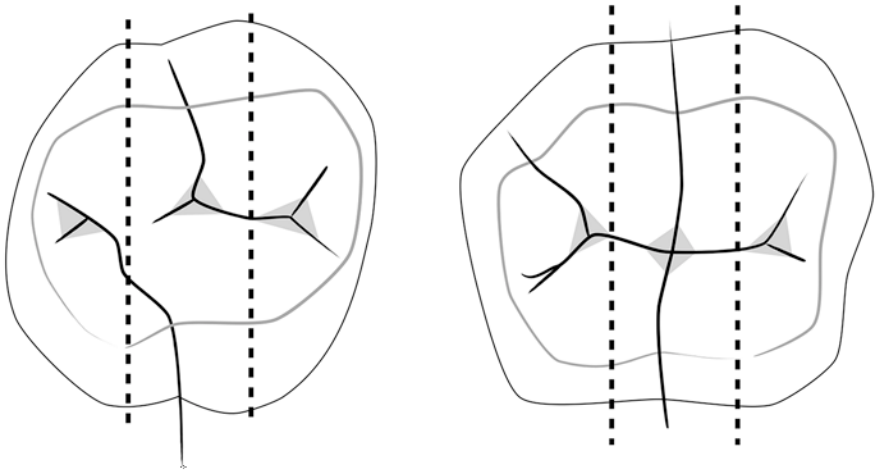

Figure 5.2 Schematic illustration of the division of the occlusal surfaces of first permanent molars into three sections. Each section was separately assessed for retention of sealants.

5.2.4 Statistical analyses

The sample for this investigation was obtained from a main study that investigated the effectiveness of protocols for treating dentine carious lesions in primary teeth (12). Focusing on the carious-lesion preventive effect of CR (79%) and ART (94%) sealants after 5 years (18), a power of 80%, a dropout rate of 30% and a correction for dependency of measurements of 20% gave a sample size of 117 sealants per group.

The statistical analyses were performed by a biostatistician using SAS version 9.2 software (Cary, NC, USA). The dependent variables were survival rate of retained sealants calculated according to the traditional and the modified retention criterion. *Traditional criterion:* A failure is determined by the total loss of sealant material on the entire surface (code 6). For the occlusal surface, all three sections should present a code 6 for the surface to be considered a failure. *Modified criterion:* A failure is determined when at least one section of an occlusal surface presents no visible sealant material (code 6).

Treatment group (CR, ART), age, gender, type of jaw, operator and baseline caries experience (D_2MFT, D_3MFT and $d_3$mft) were the independent variables. D_2 represents ICDAS II codes 1-6 and D_3/d_3 represents ICDAS II codes 4-6. ANOVA and chi-square tests were used in testing for differences between the independent variables at baseline and the treatment groups, and for the non-response analysis. The Proportional Hazard Rate Regression model (PHREG) (19) with frailty correction (20) was used to estimate cumulative survival retention rates. The Wald test (chi-square) was used to test for differences in survival rates and for estimating effects of the independent variables. The Jackknife method (21) was applied in calculating standard errors for comparison of survival rates between treatment groups per interval using a t-test. Statistical significance was set at α=0.05.

5.3 Results

5.3.1 Disposition of subjects

A total of 123 children (62 boys, 61 girls) with a mean age of 6.8 years were enrolled in the study. At baseline, 238 occlusal surfaces and 139 free-smooth surfaces in first permanent molars of these children met the inclusion criteria. Mean age, mean $d_3$mft, D_2MFT and D_3MFT counts of the participating children according to treatment groups are presented in Table 5.1.

A statistically significant difference at baseline between the treatment groups was found for age. Children in the ART sealant group were approximately two months older than children of the CR sealant group. From the 377 sealed surfaces at baseline, 274 surfaces (72.7%) were examined after 3 years and almost 30% of the sample was lost to follow-up during that period (Figure 5.1). Non-response analyses revealed no effect for treatment group (p=1.00), age (p=0.88), gender (p=0.85), baseline $d_3$mft (p=0.78), baseline D_2MFT (p=0.16) and baseline D_3MFT (p=0.38) counts.

5.3.2 Cumulative retention of sealants

Frequency distributions of fully and partially retained and fully lost sealants for occlusal and free-smooth surfaces over the 3-year follow-up period by treatment group are presented in Table 5.2. The prevalence of fully retained sealants in occlusal surfaces after 3 years was low: 15.8% for CR and 7.8% for ART sealants. The percentages of fully retained sealants in free-smooth surfaces after 3 years were 49.3 for CR and 43.8 for ART sealants (Table 5.2).

Table 5.1 Mean and standard deviations (SD) of age, D_2MFT, D_3MFT and $d_3$mft counts of participating children at baseline according to treatment group

	CR sealant		ART sealant	
	(N_{child}=78)		(N_{child}=45)	
	Mean	SD	Mean	SD
Age	6.72	0.33	6.88	0.33
D_2MFT	3.33	1.04	3.00	1.19
D_3MFT	0.26	0.55	0.33	0.56
$d_3$mft	5.86	3.08	5.80	2.33
	Age, p<0.01; D_2MFT, p=0.11 ; D_3MFT, p=0.46; $d_3$mft, p=0.90.			

N_{child}=Number of children; CR=composite resin; ART=Atraumatic Restorative Treatment.

Table 5.2 Frequency distributions of fully and partially retained and fully lost sealants for occlusal and free-smooth surfaces according to treatment group and interval

Occlusal surfaces												
	CR sealant						ART sealant					
	Fully retained		Partially retained		Fully lost		Fully retained		Partially retained		Fully lost	
Interval (yrs)	N_{Soc}	%	N_{Soc}	%	N_{Soc}	%	N_{Soc}	%	N_{Soc}	%	N_{Soc}	%
0.5	140	83.3	25	14.9	3	1.8	53	76.8	13	18.8	3	4.4
1	89	58.6	51	33.6	12	7.9	32	49.2	21	32.3	12	18.5
2	50	35.0	67	46.9	26	25.2	12	20.0	32	53.3	16	26.7
3	19	15.8	62	51.7	39	32.5	4	7.8	24	47.1	23	45.1
Free-smooth surfaces												
	CR sealant						ART sealant					
	Fully retained		Partially retained		Fully lost		Fully retained		Partially retained		Fully lost	
Interval (yrs)	N_{Ssm}	%	N_{Ssm}	%	N_{Ssm}	%	N_{Ssm}	%	N_{Ssm}	%	N_{Ssm}	%
0.5	77	89.5	6	7.0	3	3.5	40	85.1	5	10.6	2	4.2
1	67	81.7	5	6.1	10	12.2	33	73.3	4	8.9	8	17.8
2	55	71.4	4	5.2	18	23.4	22	53.6	4	9.8	15	36.6
3	35	49.3	6	8.5	30	42.3	14	43.8	2	6.3	16	50.0

N_{Soc}=Number of occlusal surfaces; N_{Ssm}=Number of free-smooth surfaces; CR=composite resin; ART=Atraumatic Restorative Treatment.

The cumulative survival rates of the two types of sealants retained in occlusal and free-smooth surfaces over 3 years using the traditional retention criterion are presented in Table 5.3. For occlusal surfaces, there was no statistically significant difference between survival rates of retained CR and ART sealants over the total 3-year follow-up period (p=0.05). However, a statistically significant difference was observed at the 1y, 2y and 3y evaluation intervals, which showed a higher retention survival rate for CR sealants. For the cumulative survival rates of retained sealants on free-smooth surfaces, no statistically significant difference was observed between the treatment groups over the 3-year period (p=0.34) nor at any evaluation interval.

Table 5.3 Cumulative survival rates (%) and standard errors (SE) of fully and partially retained sealants calculated according to the traditional criterion in occlusal and free-smooth surfaces over a period of 3 years

	Occlusal surfaces				Free-smooth surfaces			
	CR sealant		ART sealant		CR sealant		ART sealant	
Interval	%	SE	%	SE	%	SE	%	SE
0.5y	98.2	1.0	95.7	2.4	96.5	1.9	95.7	3.1
1y	91.6[a]	2.4	82.2[b]	5.5	88.0	3.6	82.4	5.7
2y	80.6[c]	4.0	67.7[d]	6.5	77.5	4.9	64.9	7.8
3y	66.3[e]	4.9	50.8[f]	8.0	56.3	6.7	49.5	9.2
	Over 3y survival model, p=0.05 [a-b], p=0.03; [c-d], p=0.02; [e-f], p=0.02				Over 3y survival model, p=0.34			

CR=composite resin; ART=Atraumatic Restorative Treatment.

The influence of independent variables on the survival model for retained occlusal sealants using the traditional retention criterion showed the following findings: no effects of gender (p=0.61), baseline $d_3$mft (p=0.47), baseline D_2MFT (p=0.07), baseline D_3MFT (p=0.41) counts, type of jaw (p=0.97), operator (p=0.14) or age (p=0.76) were found. For free-smooth surfaces, no effects of baseline $d_3$mft (p=0.60), baseline D_2MFT (p=0.83), baseline D_3MFT (p=0.28) counts, type of jaw (p=0.09) or operator (p=0.48) were found. A statistically significant effect of gender (p=0.02) and age (p=0.04) was observed for these surfaces. Boys presented higher retention rates than girls and they were slightly younger than the girls. In an adjusted retention survival model, including the variables gender, age and treatment group, no effects of treatment group (p=0.77), age (p=0.07) and gender (p=0.05) were found.

The cumulative survival rates of both types of sealants retained in occlusal surfaces over the 3-year period according to the modified retention criterion are presented in Table 5.4. For occlusal surfaces, no statistically significant difference between cumulative survival rates of retained CR and ART sealants over the total 3-year follow-up period (p=0.05) was observed. A statistically significant difference was observed at the 2y and 3y evaluation intervals, showing a higher survival rate for CR than for ART sealants. Analyses of the influence of independent variables on the survival model for occlusal sealants retention using the modified retention

criterion showed no effects of gender (p=0.70), baseline $d_3$mft (p=0.07) and baseline D_2MFT counts (p=0.09) or age (p=0.87). Statistically significant effects were found for operator (p=0.01), type of jaw (p=0.04) and baseline D_3MFT counts (p=0.04). One of the operators performed a higher number of CR sealants than the other two. For CR sealants, the retention rate in first molars of the lower jaw was higher than in those of the upper jaw (p<0.01). Type of jaw had no effect on the retention rate of ART sealants (p=0.28). The adjusted retention survival model, including operator, type of jaw, baseline D_3MFT count and treatment group, showed no effect of treatment group (p=0.22) and baseline D_3MFT count (p=0.15). Operator (p=0.03) and type of jaw (p=0.03) still presented a significant effect.

For both the CR and ART sealants, the survival model presented lower retention rates with the use of the modified retention criterion than with the traditional retention criterion over the 3-year period (p<0.01).

Table 5.4 Cumulative survival rates (%) and standard errors (SE) of fully and partially retained sealants calculated according to the modified criterion in occlusal surfaces over a period of 3 years

	Occlusal surface			
	CR sealant		ART sealant	
Interval (yrs)	%	SE	%	SE
0.5	91.1	2.3	85.5	5.8
1	70.1	4.5	60.0	7.5
2	47.6[a]	5.3	29.2[b]	6.1
3	29.8[c]	5.4	15.5[d]	5.0
Over 3y survival model, p=0.05 [a-b], p<0.01; [c-d], p=0.01				

CR=composite resin; ART=Atraumatic Restorative Treatment.

Table 5.5 Cumulative survival of cavitated dentine carious lesion-free occlusal surfaces [%(SE)], frequency distribution of cavitated dentine carious lesion location, percentage of occlusal sections with partial or fully lost sealants and retention failures at lesion detection according to the traditional and modified retention criteria

	Interval	Cumulative survival of DCav-free occlusal surfaces		$NDCav_{new}$	New lesion location		% of occlusal sections with partial and fully lost sealants	Number of occlusal surfaces considered a 'retention failure' when a cavitated dentine carious lesion was assessed, according to the retention assessment criteria	
		%	SE		Tooth	Occlusal section		Traditional	Modified
CR sealant	0.5y	99.4	0.1	1	46	od	10.3	0	1
	1y	98.1	0.6	2	16 36	od od	26.1	0	2
	2y	95.4	2.0	4	16 26 46	od, od od od	43.8	1	3
	3y	91.4	2.9	5	16 26 36 46	oc, od od oc od	63.6	3	3
ART sealant	0.5y	97.1	2.0	2	26 36	od od	15.5	1	1
	1y	97.1	2.0	0	-	-	32.8	-	-
	2y	93.9	2.0	2	36	oc, od	56.1	2	2
	3y	90.2	5.0	2	16 26	od od	73.8	1	2

DCav-free=cavitated dentine carious lesion-free surface; $NDCav_{new}$=number of new cavitated dentine carious lesions; oc=occlusal central; od=occlusal distal.

5.3.3 Loss of sealant retention and cavitated dentine carious lesion development in occlusal surfaces

Table 5.5 presents the cumulative survival rate of cavitated dentine carious lesion-free occlusal surfaces by evaluation interval, the frequency distribution of the location of the cavitated dentine carious lesions and the number of surfaces having a retention failure according to the

traditional and the modified retention criterion at the time that those carious lesions were detected.

Of the 18 cavitated dentine carious lesions that were detected (12 in the CR sealant group and 6 in the ART sealant group), 15 (83.3%) were located on the distal section of the occlusal surface. Eight cavitated dentine carious lesions occurred in lower first permanent molars and 10 such lesions in comparable teeth in the upper jaw. According to the traditional retention criterion, 8 of the 18 cavitated dentine carious lesions in occlusal surfaces (44.4%) were found on surfaces that had been determined as 'failed' for retention at the time that the carious lesion had been detected, while 14 of the 18 cavitated dentine carious lesions in occlusal surfaces (77.8%) occurred on 'failed' retention surfaces when the modified retention criterion was applied.

5.4 Discussion

5.4.1 Methodology

Sampling of the population of this study was based on the selection and randomization process of the main study, which compared treatment protocols in primary molars. From the included high-caries risk children, only first permanent molars that had erupted and also presented a high-caries risk profile at surface-level were sealed. Cluster-randomization by school was defined by the fact that two of the four public primary schools had a dental room with a fully equipped dental unit and these schools were allocated to the CR sealant group. However, as no dentist had been employed at these schools for many years, children from these schools had no expected advantage in terms of oral health care or knowledge over the children of the other two schools. Although socio-economic status was not assessed, there is no reason to believe that any difference among schools and treatment groups occurred in this aspect, since all children came from the same area of social and economical deprivation.

The sample size of the two sealants groups differed. This is not unusual in clinical trials. The main reason for the difference is most likely that the school, rather than the number of children or the number of tooth surfaces that required a sealant, was chosen as the unit of randomization. The schools that had a dental unit and that, consequently, were used for placing CR sealants contained many more children than the schools in which the ART sealant

was placed. But it is very unlikely that the unequal sample size caused a bias in the comparison of results of the two sealants groups. It is argued that, whilst an equal sample size provides the highest level of power, a deviation from it only reduces the power slightly, provided the sample size is not very low. For comparing survival results between groups, the standard error, a correction for the dependency of data within a child and the number of sealants in the group with the lowest size, are important factors. In the present study, the Jackknife standard error was calculated for compensation of the dependency of data and the lowest group size was 69 and 47 sealants in occlusal and free-smooth surfaces, respectively, falling short of the requested sample size but being large enough for a comparison between groups. Although lower than anticipated, these numbers are sufficiently high to allow for a controlled comparison between the two sealants groups.

At baseline, all caries experience counts ($d_3$mft, D_2MFT and D_3MFT) were similar between treatment groups. A slight, but significant difference of age was found. Children that received ART sealants were, on average, almost two months older than children of the CR sealant group. In the retention survival models, age was a significant factor for free-smooth surfaces only. These results support the assumption that there is no reason to presume bias in the composition of the treatment groups at start. The quality of the results is further increased by the observation that there was no difference in independent variables observed between the study and the non-response groups.

Using initial signs of carious lesions and a fissure depth classification (caries risk assessment at surface-level) as criteria for sealing pits and fissures, allowed for a more realistic assessment of the effectiveness of a sealant compared to a situation in which the caries risk is determined at child-level only (22,23). The latter approach often includes pits and fissures that are shallow and/or deep but free of a carious lesion. Without the inclusion of an assessment of the caries situation at surface level, a true comparison between sealants of different materials is not possible. However, sealing occlusal surfaces of molar teeth without a carious lesion assessment at surface level is not uncommon in sealant studies (24-26).

Resin-based sealants are preferably performed under rubber dam isolation. In the present study, rubber dam isolation was not used, as had been reported for many other sealant studies (18,25,27-30). This deviation from the going protocol for resin-based procedures is justified since it was shown that rubber dam does not improve the retention of resin-based sealants (31).

It was possible to blind treatment for the children, as only one kind of treatment was performed at each of the schools. Operators were not blinded since the sealing protocols were different. Owing to the different clinical aspects of the CR and ART sealants, it was not possible to blind the evaluators. The statistician was blinded by not knowing the meaning of the treatment group codes. The loss-to-follow-up rates were high despite the many efforts made to trace children for examination. Considering the nature of this clinical trial, we think that its internal validity is substantial but that the external validity is considered low (32).

5.4.2 Outcomes

5.4.2.1 Cumulative survival of retained sealants

The null hypothesis was accepted. No differences were found in the survival rates of retained CR and the newly formulated high-viscosity glass-ionomer ART sealants in both occlusal and free-smooth surfaces in permanent molars over the total period of 3 years according to both the traditional and the modified retention criteria. This outcome is different from that usually reported in retention studies between resin-based and glass-ionomer-based sealant materials in occlusal surfaces according to the traditional retention criterion. A reason for this situation might be the use of a potentially mechanically stronger high-viscosity glass-ionomer, the different application procedure that pushes the glass-ionomer into the pits and fissures with a finger (ART) and the fact that the generally accepted difference in retention rates between the two sealant materials has been derived from comparing results from studies that were not comparable and that had applied different retention assessment criteria (6). However, if a high-viscosity glass-ionomer ART sealant is compared to a CR sealant in one and the same study over time, using the same retention assessment criteria and performed in children of similar age, then a true comparison between the two types of sealant is possible. Comparing the results of such studies gives the following outcome: no significant difference at all 1- to 5-year interval periods (mean age: 7.8 years) (18); higher retention survival rate for CR sealants (81%) than for ART sealants (56%) after 4 years (mean age: 8 years) (33); and higher retention survival rate for CR sealants (73%) than for ART sealants (50%) after 2 years (mean age: 7.8 years) (27). The children in the present study were one year younger than the children in the studies referred to. At that age, a difference of one year can make a difference, perhaps not so much in the retention survival rate of the high-viscosity glass-ionomer, but more likely in that of the resin-composite sealant, as the latter requires a moist-free environment, which, in general, is

more difficult to obtain in on average 6.8 year olds (present study) than in on average 7.8-8 year olds (27,33). Whether age, therefore, is a reason for the difference in outcomes in the comparison between the CR and ART sealants of the present study and the Liu et al.(27) and Zhang et al.(33) studies, both of which used Clinpro and Ketac Molar Easymix as sealant materials, is difficult to say. The pattern of retention survival rates between the two types of sealants in the Beiruti et al. study (18) is strange, with a sudden steep drop in retention survival rates between years 2 and 3, and, therefore, is left out of the comparison.

The fact that the difference between the two types of sealants over the total 3-year period in the present study was of borderline significance and that a significant difference in the cumulative retention survival rate between the two types of sealants was found at the evaluation intervals of 1, 2 and 3 years, being higher for CR sealants, should not go undiscussed. That information and the 1-year younger age of the children in the present study makes it fair to conclude that, even in true comparison studies, the cumulative retention survival rate of CR sealants is probably higher than that of high-viscosity glass-ionomer ART sealants. It appears that the newly formulated high-viscosity glass-ionomer, used in the present study, did not increase the retention survival rate sufficiently, at least, to equal that of composite resin.

The present study did not show a significant difference between the cumulative retention survival rate of CR and ART sealants in free-smooth surfaces over the total 3-year period and at any of the three time intervals. This finding is different from those reported by Zhang et al (33). In that study, the cumulative retention survival rate in free-smooth surfaces after 4 years was significantly higher in CR (81%) than in high-viscosity glass-ionomer ART sealants (57%). As very few true comparison studies have been carried out using CR and ART sealants in free-smooth surfaces, it is not possible to speculate about the difference in the study outcomes.

5.4.2.2 Sealant retention assessment criteria

In the present study, the pattern of results obtained after using the modified retention criterion for calculating cumulative survival rates of the two types of sealants was similar to that of the traditional criterion. The main difference between the two retention assessment criteria concerned the significantly lower cumulative survival rates of retained sealants obtained when the modified retention criterion was applied. This finding was expected considering the

change in the definition of 'failed' retained sealant, and it is in line with results reported after 2 years (11). As the pattern of results between the two retention assessment criteria is similar and as the modified retention criterion fails a sealant earlier, would it not be better to assess sealant retention through applying the modified retention criterion instead of the traditional one, which has been used for decades? Using the former would allow the dental professional to intervene earlier by either resealing or applying other caries-preventive measures, but only if needed, if the child and/or tooth surfaces are still at a high-caries risk.

5.4.2.3 Relationship between loss of sealant retention and cavitated dentine carious lesion

Sealant retention has been used for decades as a surrogate endpoint for determining its caries-preventive effectiveness. To what extent the retention of a sealant is a prerequisite for its preventive effect has not been reported frequently (5,34,35). In the present study, 84% of the occlusal surfaces sealed with CR and 92% of those sealed according to ART were either partially or completely re-exposed after 3 years while in only approximately 9% of the sealed occlusal surfaces did a cavitated dentine carious lesion develop during the 3-year study period. This indicates that loss of sealant material does not appear to be an indicator for the development of cavitated dentine carious lesions in re-exposed occlusal surfaces. Furthermore, the manner in which retention survival of sealants was calculated appears to be related to the prevalence of cavitated dentine carious lesions. Using the modified retention criterion, a higher percentage of cavitated dentine carious lesions (78%) occurred in an occlusal surface that was assessed a failure compared to the traditional criterion (44%). Despite the fact that the percentage of cavitated dentine carious lesions was low, the finding suggests that the modified retention criterion is more suitable for indicating re-exposed occlusal surfaces at risk for cavitated dentine carious lesion development.

What appears to be clear from the present study is that solely using loss of sealant retention as a reason to reseal is an over-treatment with a questionable cost-effectiveness ratio. Therefore, sealant retention can only be considered a surrogate endpoint and, perhaps, should not be considered an endpoint at all, as was advocated recently (5). Another remarkable observation was that, although only occlusal surfaces in first permanent molars at high-caries risk were sealed, the level of caries risk in these molars, and perhaps in the mouth, probably became substantially lower over the study years. Whether this is due to the placement of the sealants (despite the low retention over the final evaluated intervals) or to the improved oral

health habits of the children over the years is difficult to say. Notwithstanding, this observation fosters the understanding that sealants are truly important but should be considered an interim treatment only for children with molar teeth that have a high risk for carious lesion development.

5.5 Conclusions

Cumulative survival rates of retained CR and ART sealants for both occlusal and free-smooth surfaces were not significantly different from each other over the total follow-up period of 3 years. The modified retention criterion presented significantly lower retention rates than the traditional criterion. Despite low retention rates, survival rates of cavitated dentine carious lesion-free occlusal surfaces were high after 3 years. Using retention survival rates as a surrogate endpoint to determine sealants effectiveness is questioned.

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CHAPTER 6

LONG-TERM EFFECT OF SUPERVISED TOOTH BRUSHING ON LEVELS OF PLAQUE AND GINGIVAL BLEEDING AMONG SCHOOLCHILDREN

This chapter will be submitted for publication as:

Hilgert LA, Leal SC, Bronkhorst E, Frencken JE. Long-term effect of supervised tooth brushing on levels of plaque and gingival bleeding among schoolchildren.

Abstract

Objective: to test the hypothesis that, in initial high-caries risk children, supervised tooth brushing (STB) will present greater reduction in levels of visible plaque and gingival bleeding compared to peers belonging to a no supervised tooth brushing group (NSTB) and receiving restorative treatment and sealants, and to an initial low-caries risk NSTB group over 4 years. *Methods:* Schoolchildren assessed as high- caries risk, aged 6-7-years, were allocated to three oral healthcare protocols using a cluster-randomized study design: (1) Ultra-Conservative Treatment (UCT), in which small cavities in primary molars were restored according to the ART approach and medium and large cavities were left opened and cleaned along all other present teeth under a daily supervised tooth brushing programme during school days at school premises (UCT/STB group; test group); (2) Conventional Restorative Treatment (CRT), in which primary molars were restored with amalgam and high-caries risk first permanent molars received composite resin sealants (CRT/NSTB group; control group); (3) Atraumatic Restorative Treatment protocol (ART), in which cavitated primary molars were restored according to the ART approach and eligible permanent molars received ART sealants (ART/NSTB group; control group). Low- caries risk children (dmft≤1) that were excluded form the trial's interventions formed another NSTB group (No-treatment/NSTB; control group). 273 children were examined at baseline (T_0) and after 4 years (T_1) according to the VPI and the GBI index. Data were analysed using linear (mean VPI at T_1) and logistic regression (mean GBI at T_1) with UCT/STB as the reference and 'mean VPI at T_0', 'mean GBI at T_0', 'combined CRT+ART/NSTB' and 'No-treatment/NSTB' as (co)variables. *Results*: The mean VPI and mean GBI scores were statistically significantly lower at T_1 than at T_0. Reduction in mean VPI scores in children of the UCT/STB group was statistically significantly higher than for the CRT+ART/NSTB children over the 4-year period but no significant difference was observed between UCT/STB and 'No-treatment/NSTB' children. No statistically significant differences in reduction of mean GBI scores were observed between the studied groups over 4-years. *Conclusions*: A higher reduction in visible plaque levels was present in children of the UCT/STB group than in those belonging to the CRT+ART/NSTB group over 4 years. There was no difference in the reduction of gingival bleeding between children that received or not tooth brushing supervision over the 4-year period.

6.1 Introduction

Dental caries is driven by the presence of a cariogenic plaque on a tooth surface. Disrupting or removing it from tooth surfaces regularly is considered the most adequate measure to prevent lesion development and progression (1,2). Daily plaque removal together with topical fluoride is the basis of any preventive program for dental caries (3).

Removing plaque is not restricted to the enamel surface and can also be performed from within cleansable cavities if they are accessible to a toothbrush and toothpaste (2,4). The effectiveness of arresting cavitated carious lesions with tooth brushing and toothpaste was demonstrated for primary teeth (5) and for root surfaces (6). This makes the necessity for restoring cleansable cavitated primary teeth questionable (7). After all, restoring a non-cleansable cavitated dentine carious lesion with a restorative material aims at removing the plaque-retentive site and at re-establishing tooth form and function, allowing easy plaque removal.

The effectiveness of an oral healthcare protocol that consisted of plaque removal from accessible and cleansable cavities in primary molars through tooth brushing with fluoridated toothpaste and restoring non-accessible cavities with the ART approach has been investigated. This protocol is termed Ultra-Conservative Treatment (UCT) and was compared to two restorative oral healthcare protocols: Conventional Restorative Treatment using amalgam (CRT) and the Atraumatic Restorative Treatment (ART) using a high-viscosity glass-ionomer (8). The clinical trial showed no significant difference in survival rates of primary molars in initially high-caries risk schoolchildren between the three protocols over 3.5 years. Plaque removal in children from the UCT group was performed under supervised tooth brushing (STB), carried out daily during school time. Children belonging to the two restorative protocols (CRT and ART) and who had a low-caries risk at start (dmft≤1) and therefore did not meet the trial inclusion criteria, were not enrolled in supervised tooth brushing activities at school (NSTB).

The question arises, if a long-term spin-off gain of daily-supervised tooth brushing exists on the status of oral hygiene and gingival health of all teeth of these children. The hypothesis tested was: that the reduction in levels of visible plaque and gingival bleeding are higher in children belonging to the UCT/STB group (test) in comparison to those belonging to the combined CRT+ART/NSTB' (control) and 'No-treatment/NSTB' (control) groups after 4 years.

6.2 Methods

6.2.1 Study design

This cluster-randomized controlled clinical trial, using a parallel group design, was carried out in all six available public primary schools of Paranoá, a deprived suburban area of Brasília, Federal District, Brazil. An epidemiological survey of the 6-7-years-old children attending those schools preceded the trial (9). Trial inclusion criteria were: 1) good general health, 2) having the consent form signed by parents or carers, 3) being assessed as high-caries risk, by having at least two cavitated dentine carious lesions in primary molars without pain or signs of pulp involvement. Eligible children were allocated, with the school as the unit, to the CRT, ART or UCT treatment protocols. Children who had been examined in the epidemiological survey and presented a dmft≤1 without signs of pulp involvement or pain were not enrolled in the trial but constituted the initial low-caries risk group.

Study design, sampling procedure and study implementation have been described in details elsewhere (8). A short description of the treatment protocols is presented below. The trial was approved by the Research Ethics Committee of the University of Brasília Medical School (reference 081/2008) and registered at the Netherlands Trial Register (reference 1699).

6.2.2 Treatment protocols

The included children were allocated into one of the three oral healthcare protocols:

Conventional Restorative Treatment (CRT) – Primary molars with cavitated dentine carious lesions were restored using rotary instruments and amalgam (Permite Regular Set, SDI, Melbourne, Australia) and high-caries risk occlusal surfaces in first permanent molars being sealed with a composite resin (Fluoroshield, Dentsply, Petrópolis, Brazil). Surface-level caries-risk assessment for first permanent molars was based on signs of carious lesion activity and fissures depth. No supervised tooth brushing activity was implemented. This protocol was termed CRT/NSTB and is a control group.

Atraumatic Restorative Treatment (ART) – Cavitated dentine carious lesions in primary teeth were cleaned using hand-instruments and restored using a high-viscosity glass-ionomer (Ketac Molar Easymix, 3M ESPE, Seefeld, Germany) according to the ART approach (10) and high-caries risk occlusal surfaces in first permanent molars being sealed with the same glass-

ionomer. No supervised tooth brushing activity was implemented and this protocol was termed ART/NSTB and is a control group. As the control groups CRT/NSTB and ART/NSTB are both related to restoring tooth cavities in initial high- caries risk children (and sealing the high- caries risk first permanent molars), they were combined in the analyses and termed CRT+ART/NSTB group.

Ultra-conservative Treatment (UCT) – Small non-cleansable cavitated dentine carious lesions were restored using the ART approach. Large and medium size dentine cavities in primary molars were left open and enlarged if needed, to allow removal of plaque through tooth brushing with toothpaste under daily supervision at school premises by a trained dental assistant between May 2009 and December 2012. From December 2012 onwards, no tooth brushing supervision was performed. Children under this oral healthcare protocol constituted the UCT/STB group (test).

The children that presented low-caries risk at start, did not receive any extra oral care and relied on the prevailing healthcare system available in the area. These children formed the second no supervised tooth brushing group (No-treatment/NSTB).

6.2.3 Implementation

At baseline, all children received a toothbrush, fluoridated (1000ppm) toothpaste (Contente, Suavetex Ltda, Uberlândia, Brazil), plaque disclosing dentifrice and dental floss and were instructed how to use it prior to the start of the trial. All restoration and sealant procedures were performed by three trained and calibrated paedodontists from May-July 2009 at school premises. Isolation was obtained through the use of cotton wool rolls. Detailed protocols of the restoration and sealant procedures are available elsewhere (8).

6.2.4 Evaluation

Plaque was determined according to the Visible Plaque Index (VPI) (11) and gingival bleeding according to the Gingival Bleeding Index (GBI) (11) by three independent evaluators (dentists) at baseline (T_0, March to June 2009) and after 4 years (T_1, March to May 2013). One evaluator participated in both examinations. Evaluators had been trained and calibrated by a senior epidemiologist (JF). Battery-illuminated dental mirrors (Kudos®, Hong Kong, China) aided the evaluation. VPI was scored as 'present' or 'absent' and expressed as the ratio of surfaces with visible plaque present related to the total number of surfaces examined. GBI was scored as

'present' or 'absent' 10s after gentle probing the sulcus using the CPITN probe (Golgran®, São Caetano do Sul, Brazil) and expressed as the ratio of bleeding sites related to the total number of sites examined.

6.2.5 Statistical analysis

The sample size was obtained from a main study that investigated the effectiveness of the oral healthcare protocols in treating caries in primary teeth (8). Statistical analyses were performed by a biostatistician using SPSS, version 20.0 (IBM Corp, Armonk, NY, USA). The dependent variables were the mean VPI score at T_1 and mean GBI scores at T_1. The independent variables were UCT/STB (initial high-caries risk children with supervised brushing) (test group), CRT+ART/NSTB (initial high-caries risk children without supervised tooth brushing) (control group), No-treatment/NSTB (initial low-caries risk children without supervised tooth brushing) (control group) and the mean VPI at T_0 and mean GBI score at T_0. The last two variables were added to correct for potential differences in the outcome at T_0 and to increase precision.

For the VPI analysis linear regression analysis was used to test the effect of the independent variables on mean VPI at T_1. The mean GBI was too skewly distributed to apply ordinary regression. Therefore logistic regression analysis was used to test the effect of the independent variables on the dependent variable 'mean GBI>0' at T_1.

6.3 Results

6.3.1 Disposition of subjects

Of a total of 835 children examined during the baseline epidemiological survey (9), 302 children met the inclusion criteria for the trial interventions and were allocated to the UCT, CRT and ART treatment protocols. Off the total of 533 children, who did not meet the inclusion criteria, 348 belonged to the initial low- caries risk group and composed the No-treatment/NSTB group. Considering the maximum number of children possible for evaluation in this study (N=650, the 4-year drop out was 58%. Figure 6.1 presents a CONSORT flow diagram of the study. Table 6.1 presents the results of background variables according to the treatment groups.

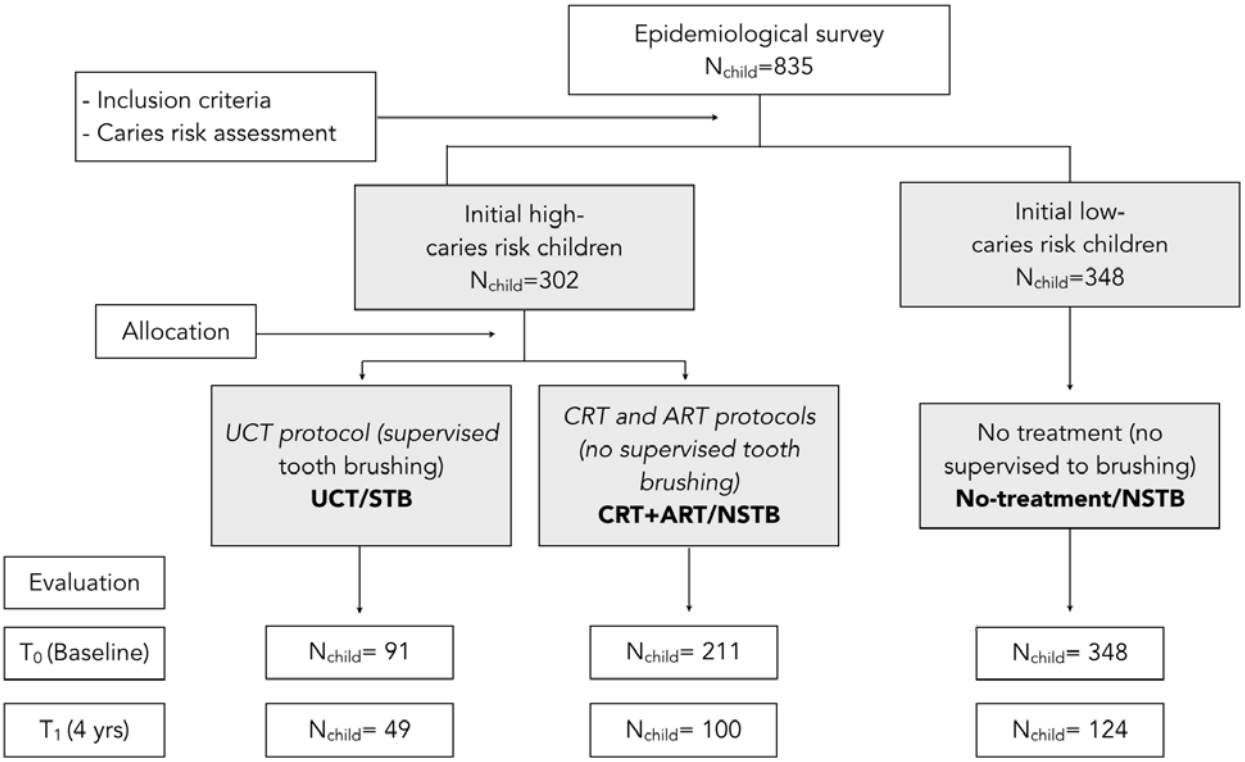

Figure 6.1 – CONSORT flow diagram. N_{child}, number of children.

Table 6.1 - Background variables at baseline according to treatment groups

	Initial high-caries risk children		Initial low-caries risk children
Treatment group	Supervised tooth brushing (UCT/STB)	No supervised tooth brushing (CRT+ART/NSTB)	No supervised tooth brushing (No-treatment/NSTB)
N of children	49	100	124
Mean Age (SD)	6.90 (0.36)	6.69 (0.36)	6.73 (0.39)
Gender (% males)	53.1	64.0	52.1
Mean $d_3$mft (SD)	5.16 (2.24)	5.63 (2.71)	0.24 (0.43)

UCT/STB = supervised tooth brushing (UCT protocol); CRT+ART/NSTB = no supervised tooth brushing (CRT and ART protocols); No-treatment/NSTB = no supervised tooth brushing (No-treatment)

6.3.2 Levels of visible plaque and gingival bleeding

The mean VPI and GBI scores of children according to the treatment groups and evaluation intervals are presented in Table 6.2. The percentage reductions in mean VPI scores were 58% for UCT/STB, 34% for CRT+ART/NSTB and 42% for no treatment/NSTB. The mean GBI scores were reduced by 57% for UCT/STB, by 73% for CRT+ART/NSTB and by 64% for No-treatment/NSTB.

Table 6.3 presents the results of the linear regression analysis regarding differences in the mean VPI scores over the 4-year period related to the treatment groups. Using UCT/STB as the reference point, the effect of CRT+ART/NSTB is 0.088 (p=0.030). The R-squared of the model is 0.03. These results show that the reduction in mean VPI scores over the 4-year period is statistically significantly higher for the UCT/STB compared to the CRT+ART/NSTB group.

Table 6.4 shows that there is no statistically significant difference between UCT/STB and CRT+ART/NSTB (OR=1.15 CI: 0.66-2.01) and No-treatment/NSTB (OR=1.12 CI: 056-2.26) on 'mean GBI>0' at T_1.

Table 6.2 – Mean Visible plaque (VPI) and mean gingival bleeding (GBI) between baseline (T_0) and after 4 years (T_1) by treatment group

Treatment group	Initial high-caries risk children		Initial low-caries risk children
	Supervised tooth brushing (UCT/STB)	No supervised tooth brushing (CRT+ART/NSTB)	No supervised tooth brushing (No-treatment/NSTB)
Mean VPI (SD) at T_0	0.76 (0.32)	0.68 (0.31)	0.60 (0.35)
Mean VPI (SD) at T_1	0.32 (0.26)	0.45 (0.32)	0.35 (0.29)
Mean GBI (SD) at T_0	0.07 (0.09)	0.15 (0.19)	0.11 (0.20)
Mean GBI (SD) at T_1	0.03 (0.06)	0.04 (0.08)	0.04 (0.07)
All differences between T_0 and T_1 are statistically significant (p<0.001)			

UCT/STB = supervised tooth brushing (UCT protocol); CRT+ART/NSTB = no supervised tooth brushing (CRT and ART protocols); No-treatment/NSTB = no supervised tooth brushing (no treatment)

Table 6.3 - Results of ordinary regression analyses regarding the mean VPI scores at T_1 over a 4-year period between UCT/STB (reference) and CRT+ART/NSTB and No-treatment/NSTB over a 4-year period

Mean VPI at T_1 (dependent variable)	Effect	95% Confidence Interval for effects		p-value
UCT/STB *(reference)*	0.333			
Mean VPI at T_0	0.042	-0.066	0.149	0.446
CRT+ART/NSTB	0.088	0.009	0.167	0.030
No-treatment/NSTB	-0.047	-0.147	0.054	0.361
R^2=0.03				

UCT/STB = supervised tooth brushing (UCT protocol); CRT+ART/NSTB = no supervised tooth brushing (CRT and ART protocols); No-treatment/NSTB = no supervised tooth brushing (no treatment)

Table 6.4 - Results of logistic regression analyses on mean 'GBI>0 at T_1' between UCT/STB (reference) and CRT+ART/NSTB and No-treatment/NSTB over a 4-year period

Mean GBI at T_1 (dependent variable)	Odds Ratio	95% Confidence Interval for OR		p-value
UCT/STB *(reference)*	0.385			
Mean GBI >0 at T_0	2.533	1.502	4.272	<0.001
CRT+ART/NSTB	1.151	0.660	2.009	0.619
No-treatment/NSTB	1.124	0.559	2.260	0.743

UCT/STB = supervised tooth brushing (UCT protocol); CRT+ART/NSTB = no supervised tooth brushing (CRT and ART protocols); No-treatment/NSTB = no supervised tooth brushing (no treatment

6.4 Discussion

6.4.1 Methodology

Children eligible to the intervention protocols were allocated using clusters of two schools for each treatment protocol (CRT, ART, UCT). The initial low-caries risk children were distributed among all the 6 schools. All schools were located in the same deprived suburban area and although no socio economical status was assessed there are no reasons to believe that any relevant differences in this aspects were presented between children of different schools.

Dropout rates were considerably high. Besides reasons as 'moving to another city' and 'irregular schools attendance' a large number of children that were in 2009 in the 2nd year of the primary education changed school after 5th grade (end of 2012) and were lost to follow-up.

An important observation in the study methodology concerns the fact that the supervised tooth brushing programme ended in the beginning of December 2012 and that the T_1 evaluation was performed from March to May 2013. This means that the children in UCT/STB group had brushed their teeth on their own for an average of 5 months. This kind of 'wash-out' period helps in determining if there was any prolonged benefit of the oral healthcare protocols after the cessation of the interventions.

6.4.2 Main findings

The hypothesis was accepted for visible plaque but it was rejected for gingival bleeding. A significant difference between the UCT/STB and the CRT+ART/NSTB group was observed regarding change in mean VPI scores over 4 years. For gingival bleeding, no difference was found between groups in the same period.

A reduction in mean VPI scores of 58% was observed for the UCT/STB, of 34% for CRT+ART/NSTB and of 42% for the No-treatment/NSTB children over the 4-year period. Although there was a reduction in mean VPI scores of children in the CRT+ART/NSTB group, the reduction was significantly less than for children in the UCT/STB group. Despite the significant reduction the explanatory effect is only 3%. This finding might be expected, but should not be acceptable, as even oral healthcare protocols that focus on operative procedures should emphasize oral hygiene measures.

That unsupervised tooth brushing may result in reduced plaque levels over time is shown for both NSTB groups, and age increase and better understanding of the significance of oral hygiene may have contributed to this outcome. Interestingly, children of the 'No-treatment/NSTB' that had not been seen by the study dentists, and most probably also not by other dentists during the study period, showed a considerable reduction in mean VPI scores that was not different from their peers in the supervised tooth brushing group. This outcome might be explained by a better oral care at home by parents or carers, a healthier less cariogenic diet, a higher standard of oral hygiene and self-care, and/or any other factor that made them belonging to the low-caries risk at the study's start.

The present study did not show a significant difference in the reduction of mean GBI scores between children of different groups. Despite the low gingival bleeding scores found at start, the mean GBI scores were significantly reduced in all groups. The fact that gingival health was measured in a mixed-dentition with teeth in a state of exfoliation and eruption may have caused false readings. One wonders if assessing gingival health should be postponed to an older age.

The present study was performed in a population with a high prevalence of caries whose children belonging to the high-caries risk protocols (UCT, CRT and ART) had at least two cavitated dentine carious lesions in primary teeth. One might, therefore, think that the interventions in these children were performed rather late. However, implementing a measure to manage and prevent carious lesions based on a 'behavioural change' towards good hygiene at a very early age (<5-6 years old) might be difficult in yielding success. At that age, pre-school children have not yet full motor self-control and rely for their routines at home on their parents/carers. Slightly older children, as those included in the present study, undergo many developmental processes and it is important to ensure that healthy behaviours in all kind of fields are established during this age (12). Therefore, one might expect preventive measures, based on acquired healthier attitudes, to be successful. As an example, compared to children that received sealants in caries prone occlusal surfaces of first permanent molars, children who brushed comparable high-caries risk tooth surfaces under supervision had no significant different rate of dentine carious lesions development over a period of 3 years (13).

In the present study, the second VPI and GBI evaluation occurred, on average, 5 months after cessation of the supervised tooth brushing in the UCT/STB group and a significant reduction in mean VPI scores was observed over the 4-year period. However, will those children keep a lower plaque level for long and will these levels remain low or even go lower? After all, there is still space for improvement as about one-third of the buccal surfaces had been recorded covered with visible plaque at T_1. The answer to this question is unknown, but age might be a factor. Lindhe and Koch (14) supervised tooth brushing in a 13-14-year-old population during three years. One year after the end of the study, children were re-examined for plaque and gingival scores and the authors concluded that there was a lack of prolonged effect of tooth brushing supervision. Unfortunately, the children of the present study cannot be reached anymore as most of them have left the primary school system.

It is concluded that for initial high- caries risk children a daily supervised tooth brushing

programme during school days at school premises resulted in a significantly higher reduction in levels of plaque than in comparable children not belonging to such a programme over 4 years. There was no significant difference in plaque reduction between initial high-caries risk children who had their teeth cleaned under daily supervision and initial low-caries risk children whose tooth brushing was not supervised. There was no difference in the reduction of gingival bleeding between children that received or not tooth brushing supervision over the 4-year period.

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CHAPTER 7

GENERAL DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

Abstract

This chapter presents a general discussion of the methodology used and main findings of the studies. The chapter ends with the conclusions drawn from the thesis and a list of recommendations.

7.1 General Discussion

This general discussion aims to consider aspects of the methodology and main findings of the five studies that lead to the overall conclusions and recommendations of the PhD thesis.

7.1.1 Clinical trials of the PhD study

The present PhD thesis is based on clinical trials that are arms of a main study that aimed to evaluate the cost effectiveness of three oral healthcare protocols designed to prevent and treat carious lesions in mixed-dentitions of schoolchildren. The rationale for the oral healthcare protocols is detailed in Chapter 1.

7.1.2 Sample, inclusion criteria, allocation, blinding and handling of data

The sample for the study was selected from an epidemiological survey among primary schoolchildren aged 6-7 that attended the six public primary schools of Paranoá (1). At this age children begin to become capable of self-performing oral hygiene and understand and learn about the importance of oral healthcare. It is also at this age that children have erupting or recently erupted first permanent molars. All these characteristics were important for the proposed design of the Paranoá Study. Also, taking into account the Brazilian educational system in which children usually need to change school when they move to the 6th grade, the inclusion of children aged 6-7 (1st and 2nd grades) was considered advantageous as it was expected to reduce the number of dropouts during the follow-up period.

To be included in the clinical trial a child had to have at least two cavitated dentine lesions without pulp involvement in primary molars and had to be in good general health. That goal was achieved during the initial epidemiological survey, as among the 835 children assessed it was possible to identify 302 children who met the inclusion criteria. However, a much higher $d_3$mft than the one expected for this population was found. Children included in the trial presented a mean $d_3$mft of more than five. It is questionable whether patients with such a high caries experience should be defined as only 'high-caries risk'. They were already 'sick' and presented advanced stages of the disease (ICDAS II, carious lesions codes 5 and 6). Therefore, a complementary strategy of selecting first permanent molars with indication to be sealed was adopted, based on a surface-level caries risk assessment, in which signs of carious activity and depth of fissures were considered. Using this approach, high-caries risk surfaces

were selected and a true comparison of surfaces that already presented signs of carious activity at baseline could be performed among the selected oral healthcare protocols. Also, by not sealing the low-caries risk surfaces, over-treatment was avoided.

In Paranoá, only two of the six schools had dental offices. Neither of these offices had been used for many years since no dentist was employed at either of the schools. The research team re-activated these offices to allow the performance of the restorations and sealants of the CRT oral healthcare protocol, which required rotary instruments and moisture control using suction devices. Since the CRT oral healthcare protocol could not be performed in all six schools, it was decided to allocate patients to the oral healthcare protocols using a cluster-randomised design, with the school being the unit. The CRT oral healthcare protocol was conducted in the schools that had dental offices and the ART and UCT oral healthcare protocols were randomly allocated to the remaining schools, each oral healthcare protocol being executed in two schools. The analysis of background variables showed that this allocation process did not generate considerable bias, as children from the six schools were comparable. On the other hand, the necessity of performing this quasi-randomisation process exhibits a limitation of the CRT oral healthcare protocol in the technical requirements that may limit its implementation. This is an important issue, particularly when lack of access to dental treatment is taken into account.

In clinical trials, blinding of all subjects involved in the study is desirable to avoid performance and detection biases. In the Paranoá Study, operators and evaluators could not be blinded. The CRT, ART and UCT oral healthcare protocols had different execution procedures. Restored and sealed teeth using different materials and teeth that received only supervised tooth brushing were visually distinct, which compromised blinding of operators and evaluators. It is arguable that patients' blinding was adequate, since children in the same school received just one kind of oral healthcare protocol and for the absolute majority of children the Paranoá Study was their first ever contact with professional dental care.

Lack of operators and evaluators blinding is not uncommon when dealing with protocols that are different in nature and visually distinguishable. This situation is known and the Cochrane Collaboration Group Manual (2) suggests that a thorough analysis of how the lack of blinding may affect a particular outcome should be performed when assessing the risk of bias of a study. Therefore, it is my opinion that when a study design is adequate, but circumstances make blinding impossible, the quality of evidence generated by that study

should not be downgraded. When comparing distinguishable protocols and/or materials, systematics reviews should be careful about concluding that more high quality evidence is required as the findings of some existing studies are considered to be of low quality solely based on their lack of blinding. In such comparisons, high quality evidence may never be achieved. Alternatively, it could be suggested that if a number of clinical trials on a specific topic, carried out in different places of the world and in different populations, point in the same direction, the collection of these results could provide high quality evidence about that topic.

When dealing with longitudinal data in clinical trials, as are those data presented in this thesis, it is not uncommon to find missing observations in the database, which hinders a smooth analysis and interpretation of the data. In the present study, when a missing score from the database was followed by a subsequent observation, a logical (deductive) imputation of a score (e.g. a missing observation was considered a success because the subsequent score was a success) could be performed in most cases. In the very few situations in which it was not possible to define the exact moment of failure, it was decided to allocate missing observations between 'having survived' and 'having failed' in an alternating manner. The imputation process is important for increasing the consistency of the database and was used in the Paranoá Study whenever a subsequent observation was adequate, under statistical orientation.

In compliance with the CONSORT statement for reporting clinical trials (3), all studies of the thesis reported the dropout rates and reasons for the dropouts. Non-response analyses were performed whenever possible. Dropout rates were acceptable and in the expected range (approximately 10% per year) for the studies presented in Chapters 2, 3, 4 and 5. A higher dropout rate was observed in the last study of the thesis (Chapter 6) and the main reason (children moved to other schools) presented.

Therefore, the main methodological issues that could create significant biases for the clinical trials were clearly reported and all possible actions taken to reduce the risk of such biases.

7.1.3 Survival of restorations in primary molars

The study presented in Chapter 2 shows that the cumulative survival rates of amalgam and ART restorations are not significantly different over 3 years and that multiple-surface restorations fail more frequently than single-surface ones.

At the specific 3-year evaluation interval, amalgam restorations presented a higher survival rate in multiple-surface cavities. Based only on this finding, it is not possible to conclude that restoring such cavities according to the CRT protocol is to be preferred. Moreover, a systematic review that compared different materials for restoring proximal lesions concluded that the ART technique performed no differently from the other materials tested. The authors of this systematic review affirm that an ideal restorative approach for such lesions is not available yet (4). Additionally, a Cochrane systematic review that aimed at comparing different filling materials for restoring primary teeth concluded that insufficient evidence is available to make any recommendations about which restorative material to use (5).

In that regard, promising products are being proposed. The present thesis investigated a newly developed high-viscosity glass-ionomer cement (HVGIC). The use of this material, which has higher fracture toughness (6) than its predecessors, may be the reason that ART restorations achieved a higher survival rate in this study than those of a systematic review conducted in 2012 (7). However, the unsatisfactory results of multiple-surface restorations at longer evaluation intervals and early wear, aesthetics and restricted use in permanent teeth present a case for continuous development of the HVGICs.

While amalgam use has been set to be phased down following the Minamata Convention (8), many companies have launched improved HVGICs with better mechanical properties onto the market (9,10). It is to be expected that the clinical results of HVGIC restorations would be even better with these newer materials, as some recent studies suggest (11,12).

Moreover, the ART protocol causes less pain and anxiety, especially for young children and when the operator is not a specialist in paediatric dentistry (13,14); is more accessible than the CRT; and is suggested to cost less (15). There are reasons to believe, therefore, that HVGIC restorations used in the ART approach may succeed conventional amalgam restorations as the main restorative protocol for treating primary molars.

7.1.4 Survival of teeth with defective and intact restorations

In the study presented in Chapter 2, the question on what happened to the primary molars that presented defective restorations motivated the follow-up of the natural course of all the teeth that were restored, using CRT or ART. Survival of teeth that presented a restorative defect was

compared to the survival of teeth that had intact restorations throughout the investigated interval.

Tooth survival was higher for molars with intact restorations (97.5%) than for those with defective ones (76%) over 2 years. The observation of a high tooth survival for both groups (teeth with defective and with intact restorations), despite the significant difference between them, raises the question: is it necessary to replace or re-restore primary molars that present a restorative defect?

Very few studies were found that dealt with this issue. In those studies that did, reports of re-exposed dentine being hard and dark in colour (16) and that usually no carious lesion progression was observed in teeth with defective restorations (17) support the findings of the present thesis. It was suggested that cavity preparation may remove soft dentine, which enables self-cleaning, and that dentine hypermineralisation may occur under restorations. Also, an increase in the age of children may be accompanied by better oral hygiene and plaque removal (as shown for the 'no supervised tooth brushing' groups discussed in Chapter 6). Access to fluoride sources may be a very important factor in arresting the progression of caries in re-exposed cavities.

It is interesting to observe that the main type of restorative defect found in the study described in Chapter 2 was 'most or all restoration is missing'. This meant that the majority of teeth that had defective restorations were 'without a restoration', with an opened cavity. Most restorations defects were found in those restored cavities that involved multiple surfaces, usually larger in extension than the more successful single-surface restorations. This rationale allowed the findings of studies that questioned the need for restorations in treating cavitated-dentine carious lesions in primary teeth to be brought to the discussion.

Two retrospective studies from Great Britain found that most unrestored primary teeth exfoliated without symptoms (18) and no difference was found in the rate of pain or sepsis between restored and unrestored primary teeth (19). In China, a recent prospective study that followed up restored and unrestored primary molars for 3.5 years presented similar results (20). In the Paranoá Study, the results of the UCT oral healthcare protocol, which restored small non-cleansable cavities using the ART approach, widened medium and large cavities and established a daily supervised tooth brushing programme, were no different from the results of the restorative CRT and ART protocols regarding tooth survival after 3.5 years (21).

Primary teeth have a definite lifespan. Those that present a defective restoration may not require repair or re-restoration if exfoliation is expected soon. Even in teeth that may remain in function for a longer time (younger children), if a child's plaque removal is good, sources of fluoride are available, and the cavity is accessible to toothbrush and toothpaste, a re-restoration may not be needed.

7.1.5 Caries-preventive effect of supervised tooth brushing and sealants

Findings of the study presented in Chapter 4 show no difference in survival of dentine cavitated carious lesion-free high-caries risk occlusal surfaces of first permanent molars over 3 years among composite resin (CR) sealants, HVGIC ART sealants and supervised tooth brushing (STB). In low-caries-risk occlusal surfaces, no difference between supervised tooth brushing and no supervised tooth brushing was observed regarding survival of dentine cavitated carious lesion-free first permanent molars.

Sealants are proven effective measures in preventing carious lesions in high-caries risk children (22). ART and CR sealants were no different in their caries-preventive effect, which is in line with other studies of the current literature (22-25). ART sealants present the advantage of better accessibility (can be performed at schools that do not have a dental office) and improved moisture tolerance, which are particularly relevant in erupted and recently erupted teeth.

When compared to both sealing protocols in high-caries risk surfaces of first permanent molars, daily at school premises did not present any difference regarding the prevention of dentine cavitated carious lesions. While supervised tooth brushing requires the continuous work of trained personnel (such as the dental assistant in the Paranoá Study), sealants require dentists. Moreover, long-term benefits of preventing carious lesions through methods based on encouraging and improving oral hygiene should be taken into account when calculating the cost effectiveness of such protocols.

Low-caries risk surfaces of first permanent molars that received or did not receive supervised tooth brushing presented a similar survival rate of dentine cavity-free occlusal surfaces. This finding suggests that intensive preventive actions (such as supervised tooth brushing or placing sealants) are not required for teeth that do not show signs of carious lesion activity, despite the child being initially assessed as high-caries risk. This corroborates the

opinion that intensive preventive actions in all permanent molars irrespective of a surface-level caries-risk assessment may be considered an over-treatment (26).

An interesting finding was that lesions with enamel breakdown (ICDAS II code 3) of the STB group did not progress. Approximately 20% progression was found in sealed ICDAS 3 lesions. Despite the low number of lesions, this finding supports a Minimal Intervention Dentistry approach for such lesions. The possibility of controlling carious lesion progression solely by supervised tooth brushing may even change current recommendations, which indicate sealing to manage initial carious lesions (enamel breakdown) in occlusal surfaces (27).

It is worthwhile mentioning that no localised tooth brushing was performed in the first permanent molars of the STB group that presented high-caries risk. Regular and frequent plaque disruption/removal with toothbrush and fluoridated toothpaste of the whole mouth was as effective as sealing specific molars.

7.1.6 Survival of retained sealants

Retention of sealants is commonly used as a surrogate endpoint for evaluating effectiveness of sealing in preventing caries. The findings presented in Chapter 5 demonstrate that ART and CR sealants did not differ in the survival of retained sealants over 3 years. However, CR sealants presented higher retention survival rates for occlusal surfaces at longer evaluation intervals.

The retention of CR sealants has been shown to be higher than that of ART sealants in recent studies that have used comparable methods and materials to those of the present study (28,29). Differently, however, children in the other studies were 1 to 1.2 years older than those of the Paranoá Study. In the present thesis, this fact may have jeopardised CR retention, since younger children may present more difficulties regarding correct moisture control during sealing procedures of first permanent molars.

In calculating survival, a success/failure dichotomy needs to be established. The traditional criterion for assessing retention as a failure is a complete loss of retention. In occlusal surfaces that are evaluated by sections (thirds), all three sections need to show complete loss for a sealant to fail for retention. However, if retention were a determinant of a sealant's success, just a section of the surface of pits and fissures re-exposed to the oral environment would be enough to increase the risk of the development (or progression) of a carious lesion. Therefore, a stricter criterion was suggested, in which a single section with

complete loss of sealant material already fails the sealant for retention. This approach to calculating the survival of retained sealants was named 'modified criterion' (30).

The findings of the present study showed a similar pattern of survival of retained CR and ART sealants using the traditional and modified criteria. However, retention rates were much lower using the modified criterion. When looking for a relationship between loss of sealant retention and the development of a cavitated-dentine carious lesion in occlusal surfaces (based on the results of the study presented in Chapter 4), it was observed that, despite very low retention rates, a high survival rate of cavitated dentine carious lesion-free surfaces was found. Also, the modified criterion was more 'sensitive' in assessing, as failed for retention, surfaces in which cavitated dentine lesions occurred (however, with a very low 'specificity').

The results of the study presented in Chapter 5 support recent questioning of the use of the survival of retained sealants as a surrogate endpoint for sealant effectiveness in preventing caries (31). Re-sealing a missing sealant and judging a sealant as ineffective for not being retained after some years of service do not seem to be correct ways of increasing the caries-preventive effect or interpreting sealant success in preventing development of carious lesions.

It is my thought that sealants play an important preventive role at certain of a child's life, mainly as an interim treatment in high-caries risk erupting and recently erupted molars. When the child's oral health habits are improved (with age and education towards more healthy behaviours), retention of sealants does not seem to be as important in surfaces that are accessible for plaque removal/disruption. Therefore, the findings of this study suggest that the decision to re-seal should be based on factors such as age, eruption stage (occlusion), access to toothbrush and toothpaste, standards of oral hygiene, sources of fluoride and living conditions.

7.1.7 Supervised tooth brushing effect on visible plaque and gingival bleeding levels of schoolchildren

All children in the sample presented significantly less plaque and gingival bleeding at the age of 10-11 (4 years after the commencement of the study) than when they were 6-7 years old, despite being initially assessed as high- or low-caries risk or being included in an supervised tooth brushing programme or not. As children become older they increase the self-capability

of performing adequate tooth brushing and may better understand the significance of oral hygiene.

The initial high-caries-risk children of the STB group presented increased reduction in plaque levels than those that were not supervised during tooth brushing. This finding demonstrates that the supervised tooth brushing scheme not only effectively controlled carious lesion progression in cavitated dentine lesions in primary molars and in enamel carious lesions in first permanent molars but also assisted children in establishing better self-tooth cleaning, which is expected to have a long-lasting effect.

7.1.8 Oral healthcare protocols for preventing and treating carious lesions in mixed-dentitions

On the basis of the results of the studies reported in this thesis and other publications of the Paranoá Study, it is possible to conclude that the three oral healthcare protocols (CRT, ART and UCT) were similarly effective in treating cavitated carious lesions in primary molars and in preventing the development of cavitated dentine carious lesions in first permanent molars. This suggests that issues other than effectiveness should be taken into account when discussing the strengths and weaknesses of these oral healthcare protocols.

CRT has been used for decades, requires dentists and dental offices and may have a negative impact on a child's acceptance of treatment due to anxiety and pain. This conventional protocol has been shown to be inaccessible to populations of deprived communities such as those in Paranoá (1). The lack of access to dental care of these communities has been confirmed by the results of Brazil's oral health survey of 2010 (SB Brasil 2010), which showed that 80% of carious lesions in primary teeth were untreated (32). Also, recently published results of the 2013 National Health Survey showed that only 44.4% of the Brazilian population had visited a dentist in the 12 months prior to the survey (33). Accessibility to treatment is a key issue in Brazil, and protocols that increase access to treatment for the population need to be tested, accepted and implemented.

It is known that many dentists in Brazil cannot work continuously because of problems in the functioning of existing dental equipment, which compromise the implementation of protocols that require such equipment. This results in the public not receiving adequate care. The ART approach has been created as a response to the lack of access to oral healthcare by deprived populations. This approach does not require a dental chair, and even electricity and running water are unessential. In the Paranoá Study, ART restorations and ART sealants were

placed without difficulty. If the CRT oral healthcare protocol had been chosen for application in all primary schools, the study would have been more cumbersome and costly to carry out due to technical constraints. However, despite the fact that the ART oral healthcare protocol increased accessibility, it is necessary to complement this caries management approach with an intensive education programme on the causes and ways of preventing dental caries for achieving a long-term effect. It is, therefore, important to highlight that all children that participated in the trial received, at baseline and also during the oral health protocols evaluations, instructions about good oral health habits. The difference between the oral healthcare protocols was that children from the UCT oral healthcare protocol received reinforcement every school day during supervised tooth brushing sessions.

The question that needs to be answered now concerns the cost effectiveness of these oral healthcare protocols. Are the advantages of the ART approach in making oral healthcare accessible relevant when the costs of implementing such a protocol are taken into account? The ART approach seems to be twice as cheap as the conventional amalgam restorations (15).

Is the UCT oral healthcare protocol, which in the studies reported on in this thesis involved daily tooth brushing supervision during school days, feasible in terms of costs? Is the daily supervision necessary, or could supervised toothbrushing be performed at longer intervals? Is a dental assistant needed or could teachers be trained to perform such supervision? Modifications in the interval between supervisions and in the person who executes the ultra-conservative protocol needs further investigation. As this is the first time that such a protocol has been tested, more clinical trials are needed to confirm the results presented here.

Non-operative caries treatment and prevention programmes may be even costlier than conventional protocols (34). However, long-term benefits may outweigh the costs (34). Little scientific attention has been paid to the cost effectiveness of dental care, and economic evaluations in preventive dentistry are scarce. Further research in this area is encouraged (34).

The cost effectiveness of the Paranoá Study's protocols is the main outcome of the whole study and the results are expected to be available in the near future. However, independently of the costs, the ART and the UCT oral healthcare protocols may be the only viable options for providing care for those who do not have access to the conventional way of managing carious lesions. As the results of the present study showed that the ART and UCT oral healthcare protocols presented similar effectiveness compared to the conventional protocol, the choice of treatment should not be related to the effectiveness of care only but

also to other factors such as professional preference, environment, dental education, and ratio of dentists/patients in the population.

If preventive measures and treatments for existing lesions that act on the factors that cause the disease (and are not focused simply on 'filling' or 'covering' the signs and symptoms of it) are proven effective, and costs are acceptable, it seems more logical that such oral healthcare protocols should be elected as a first choice. A paradigm shift towards Minimal Intervention Dentistry may contribute to avoiding the 'tooth death spiral' (35), and more patients will keep their teeth healthy and functional for life. It is my opinion that many deprived communities with similar characteristics as those in Paranoá may benefit from the outcomes of this thesis through establishing improved pathways to providing effective oral healthcare.

7.1.9 The Paranoá Study and oral health of the local schoolchildren

The clinical investigations presented in this thesis and as part of the Paranoá Study have contributed to the oral health of schoolchildren in two ways: by increasing access to oral healthcare and by gathering knowledge for developing health-maintaining interventions for future use.

The epidemiological survey that was carried out prior to the implementation of the oral healthcare programmes tested in primary schools in Paranoá showed that children, in most cases, had never seen a dentist. Moreover, considering what is known about the oral healthcare system in that locality, it is assumed that this situation would not have changed if the children had not been enrolled in the study. Why is that? The population in Paranoá is considered to be of great vulnerability and relies solely on the Public Oral Healthcare system to solve their oral health problems. However, due to the imbalanced ratio between the number of people to be treated and the number of dentists working at the Public oral health centres, parents face the great difficulty of having to take days off from work to bring their child to the dentist in cases of pain. Add to this the low value that the community gives to oral health in general and, most probably, the child would have the tooth extracted in the case of pain. The Paranoá Study showed that by taking the dentist to the school a large number of children could be treated preventively and restoratively. In a period of 3 months, 3 operators working for half a day were able to restore 750 teeth and to seal 377 surfaces. In that way, this programme did not only benefit the children enrolled in the oral healthcare programmes but

has the potential to benefit many more, as the reality encountered in Paranoá is exactly the same as that observed in many others parts of the country.

The fact that no difference was observed in the success rate of the more accessible and non-conventional oral healthcare protocols ART and UCT in comparison to the traditional 'drill and fill' protocol encouraged the researchers to discuss the best strategy for implementing the study outcomes within the health and school systems of Paranoá with the local health and educational authorities. The discussions revealed that ways should be found of bringing ART and UCT to the schools, including into the school curriculum information, and that exercises regarding prevention of oral diseases and how to keep teeth healthy should support this suggestion. Similarly, public health dentists employed in Paranoá should be educated in the principles and application of ART and in the advantages and indications of keeping cavities in primary teeth plaque free with toothbrush and toothpaste containing fluoride. In this way, the current lack of access to oral healthcare could be counteracted.

The study also provided essential knowledge regarding the possibility of maintaining high-caries risk occlusal tooth surfaces (in permanent molars) free from cavitated dentine carious lesions. Knowledge of this topic is rather rare and the study has contributed to the development of health-maintaining programmes that are attainable for people who can afford a toothbrush and a fluoride-containing toothpaste on a regular basis. Similarly, the study regarding keeping tooth cavities plaque free is the first of its kind. It obviously needs further investigation but the major outcome is important: medium- to large-size cavities, which are difficult to restore and which result very frequently in low survival rates, may not need to be restored in all cases at all. This very interesting result should be capitalised. Regular supervised tooth brushing, and brushing of tooth cavities in primary teeth regularly, may become the cornerstones for a new, appropriate, oral healthcare programme that may be able to keep the children of Paranoá and, for the same matter, those in other satellite cities of Brasilia, free from tooth cavities or, at least, reduce the burden of these cavities for them. Cooperation with local leaders and those of the federal government in Brasilia should, therefore, take place. Without their support, the results of the presented studies in this thesis may remain underutilised.

7.2 Conclusions

On the basis of the main findings of this PhD research, it is possible to conclude:

1. No difference was found in the cumulative survival rates of conventional restorations using amalgam and high-viscosity glass-ionomer ART restorations in the primary molars of 6-7-year-old children over 3 years (Chapter 2);
2. Multiple-surface conventional and ART restorations in primary molars presented lower cumulative survival rates than single-surface restorations (Chapter 2);
3. Primary molars with defective restorations were extracted more frequently than comparable restored teeth with intact restorations. Survival rates of primary molars with both defective and intact restorations were high (Chapter 3);
4. There was no difference in the caries-preventive effect of composite resin, high-viscosity glass-ionomer ART sealants and daily supervised tooth brushing at school premises in high-caries risk occlusal surfaces of first permanent molars of children aged 6-7 (Chapter 4);
5. In low-caries risk occlusal surfaces of 6-7-year-old children, no difference was observed in the cumulative survival rate of cavitated dentine carious lesion-free surfaces over 3 years between daily supervised tooth brushing at school premises and no intervention (Chapter 4);
6. The cumulative survival rate of retained sealants was not significantly different between composite resin and high-viscosity glass-ionomer ART sealants placed in high-caries risk occlusal surfaces of first permanent molars of 6-7-year-old children over 3 years. A significantly higher retention rate was observed for composite resin sealants at longer evaluation intervals (Chapter 5);
7. Children who were submitted to an oral healthcare protocol that included daily supervised tooth brushing at school premises presented a higher reduction in levels of visible plaque than children who received oral healthcare protocols based on restorations and sealants without supervised tooth brushing after 4 years (Chapter 6).

7.3 Recommendations

1. Restoring cavitated dentine carious lesions in primary teeth is the most accepted way of managing those lesions. The present thesis showed that conventional amalgam restorations and high-viscosity glass-ionomer ART restorations in primary molars survive equally long over 3 years. Therefore, since ART is a more accessible, less equipment-requiring procedure that causes lower levels of pain and anxiety and appears to be cheaper than conventional restorations, it should become the standard restorative procedure for primary teeth. The ART approach should be widely introduced into the public health service and in dental training institutes in Brazil and in other countries. Instruction material and basic education on the ART technique should be improved and be made widely available in Brazil.
2. The oral healthcare protocols investigated in this thesis were shown to be as effective as the conventional way of managing dental caries in Brazil's public oral health centres, which is based on restoring primary molars with amalgam and sealing first permanent molars with resin-based sealant materials. However, it is believed that the majority of dentists that are currently working in the public sector are not adequately trained in ART, neither is the glass-ionomer of high-viscosity available at the oral health centres. Therefore, before implementing protocols that rely on ART, it would be necessary to train the dental staff properly and provide them with material of good quality.
3. To help in understanding when and if it is necessary to re-restore or repair a defective restoration in primary molars, future clinical trials should assess not only the survival of restorations but also the survival of teeth, and should examine the effects of defective restorations on exfoliation patterns and quality of life.
4. Sealants are indicated for high-caries risk surfaces of permanent molars in high-caries risk children whenever an intensive and frequent supervised tooth brushing programme is not available. The type of sealant, composite resin or high-viscosity glass-ionomer ART, does not seem to influence the caries-preventive effect. Therefore, as the ART approach increases the accessibility to restorative and preventive care and as the high-viscosity glass-ionomer is more moisture-tolerant during the tooth eruption process, ART sealants are the first choice for sealing caries-prone tooth surfaces.
5. The UCT oral healthcare protocol was as effective as the CRT and the ART protocols in treating cavitated dentine lesions in primary molars and preventing cavitated dentine lesions

in first permanent molars. As a spin-off benefit, children of the UCT protocol presented improved reduction in visible plaque levels after 4 years. As only a few studies have investigated the effect of plaque removal from tooth cavities, more such studies are required before the UCT can be considered an evidence-based treatment. Nevertheless, the outcomes of the UCT protocol should be made available to as wide an audience as possible within and outside Brazil.

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CHAPTER 8

SUMMARY

SAMENVATTING, CONCLUSIES EN AANBEVELINGEN

RESUMO, CONCLUSÕES E RECOMENDAÇÕES

8.1 Summary

This PhD thesis is based on five studies that aimed to investigate the effectiveness of different oral healthcare protocols on the prevention and treatment of carious lesions in the mixed-dentition of schoolchildren aged 6-7 in Paranoá.

Chapter 1 presents an overview of the Paranoá Study and the rationale and aims of the present PhD thesis. The Paranoá Study covers many different research topics such as epidemiology, dental anxiety and pain, quality of life, restorative treatment, caries prevention, cost effectiveness and laboratory investigations. The Study began by assessing the oral health situation of children of Paranoá, a suburban area of Brasília that presents a lower Human Development Index score than the average for Brazil's capital city. The oral health epidemiological survey conducted in 2009 revealed that schoolchildren aged 6-7 presented a high prevalence of dental caries in primary and permanent dentition and a high mean caries experience in primary dentition and that most of the cavitated dentine lesions in primary teeth were untreated. This situation called for developing and investigating oral healthcare protocols that would provide treatment for the existing carious lesions in primary teeth and prevent new carious lesions, particularly in the erupting permanent dentition. Furthermore, the oral healthcare protocols would need to improve access to oral care in this deprived area.

The oral healthcare protocols investigated in the Paranoá Study are:

Conventional Restorative Treatment (CRT), consisting of restoring primary molars using rotary instruments and amalgam, and sealing high-caries-risk surfaces of first permanent molars using composite resin (CR) sealants;

Atraumatic Restorative Treatment (ART), consisting of restoring primary molars using a high-viscosity glass-ionomer cement (HVGIC) according to the ART approach, and sealing high-caries risk surfaces of first permanent molars with HVGIC ART sealants; and

Ultra-conservative Treatment (UCT), consisting of restoring small non-cleansable cavities in primary teeth using ART and leaving medium and large cavities open, and enlarging these when needed for allowing access for cleaning the cavity. Cleaning is performed with toothbrush and fluoridated toothpaste at school premises under daily supervision during school hours. The high-caries risk surfaces of first permanent molars were cleaned during this activity. No sealants were placed.

The CRT oral healthcare protocol was considered the control group and the ART and UCT oral healthcare protocols the test groups. Chapter 1 also presents results of sub-studies of the Paranoá Study that had been carried out already. Finally, the rationale and the aims of the PhD are described. The aims are: (1) to compare cumulative survival rates of amalgam and ART restorations in primary molars over a 3-year period; (2) to compare cumulative survival rates of primary molars with intact and defective amalgam and ART restorations; (3) to compare the effectiveness of two types of sealants and supervised tooth brushing (STB) in preventing dentine carious lesion development in high- and low-caries risk occlusal surfaces of first permanent molars over 3 years; (4) to compare the cumulative survival rate of retained CR and a newly formulated HVGIC ART sealant in first permanent molars over a period of 3 years using two retention assessment criteria; and (5) to evaluate the effectiveness of supervised tooth brushing on levels of biofilm and gingival bleeding in comparison to non-supervised tooth brushing over a period of 4 years.

To see whether HVGIC ART restorations perform better than CRT restorations in primary molars was the aim of the study presented in **Chapter 2.** The study was a cluster randomised clinical trial using a parallel group design that compared the cumulative survival rate of amalgam and ART restorations in primary molars over 3 years. A total of 280 children aged 6-7 and who presented at least two cavitated dentine carious lesions in primary molars without pain or pulpal involvement were included in the study. A total of 364 amalgam restorations (126 children) and 386 ART restorations (154 children) were placed by three trained and calibrated paedodontists and evaluated at 0.5y, 1y, 2y, and 3y using the ART restoration criteria by two independent and calibrated examiners. The cumulative survival rates over 3 years for all, single- and multiple-surface amalgam restorations (72.6%, 93.4%, 64.7% respectively) were no different from those of comparable ART restorations (66.8%, 90.1% and 56.4% respectively). Multiple-surface restorations presented significantly lower survival than single-surface restorations for both treatment protocols. The main reasons for restorations failures were mechanical (94.8%) while secondary caries occurred in only 5.2% of failures. No differences in reasons for failures were observed between treatment groups. The survival rates of ART restorations in single- and multiple-surfaces were higher than those of a meta-analysis on ART restorations (66% and 31% respectively). This was expected and may be ascribed to the use of a newly marketed (at the time the study began) HVGIC with a higher than usual powder-to-liquid ratio and better mechanical properties. However, at the interval of 3 years,

multiple-surface amalgam restorations presented significantly higher survival rates than comparable ART restorations. The 43.6% failure rate in multiple-surface ART restorations after 3 years versus 35.3% for amalgam restorations indicates that improvements in these ART restorations are still needed. The study concludes that HVGIC used in conjunction with the ART approach may be considered a viable alternative to conventional amalgam restorations in restoring single-surface cavities in primary molars.

During the evaluations of the clinical trial it was noticed that a large number of defective restorations did not cause any harm to the child neither were many of such teeth seen with an abscess or fistulae. This raised the question of whether defective restorations need to be re-restored, which is the treatment commonly accepted, as there was a high chance that such teeth would exfoliate without pain or sepsis. Therefore, additional analyses, which compared the cumulative survival rates of primary molars with intact and defective amalgam and ART restorations, were carried out (**Chapter 3)**. 649 restored primary molars, of which 162 were assessed with defective restorations for mechanical reasons were followed over a period of 3.5 years. Teeth with defective restorations were followed from the time they were assessed defective. Restored primary molars that had been extracted because of the presence of dental sepsis or toothache were considered a failure. The survival rate of primary molars with intact restorations (97.5%) was statistically significantly higher than for those with defective restorations (75.9%) over a 2-year period. No effect of treatment protocol (amalgam or ART) or of type of surface (single or multiple) was observed. It was concluded that, despite the higher rate of extraction for primary molars with defective restorations than for those with intact restorations, the survival rates for primary molars with defective and intact amalgam and ART restorations were high. This suggests that when to re-restore defective restorations in primary teeth needs to become a topic of discussion.

Chapter 4 presents a cluster randomised controlled clinical trial that aimed to investigate the effectiveness of three caries-preventive protocols on high- and low-caries risk occlusal surfaces of first permanent molars over 3 years. Some 242 schoolchildren, 6-7 years old, from the low socio-economic area of Paranoá and presenting a high-caries risk at the patient level, were included in the study. Initially, pits and fissures of first permanent molars were assessed for caries risk at tooth-surface level, using a combination of ICDAS II and fissure depth codes (high-caries risk was determined by ICDAS II codes 2 and 3 or a combination of ICDAS II code 1 and medium or deep fissures). High-caries risk occlusal surfaces were treated

according to three protocols: daily supervised tooth brushing at school premises (STB), composite resin (CR) and HVGIC ART sealants. Low-caries risk occlusal surfaces received STB or no intervention. Two independent and calibrated examiners evaluated the children at 0.5y, 1y, 2y and 3y. A cavitated dentine carious lesion was considered a failure. Over 3 years, there was no significant difference in the cumulative survival rates of cavitated dentine carious lesion-free high-caries risk occlusal surfaces. Cumulative survival rates were 95.6%, 91.4% and 90.2% for STB, CR and ART sealants respectively. For low-caries risk occlusal surfaces, no significant difference was observed between the cumulative survival rate of dentine carious lesion-free surfaces between STB (94.8%) and no-intervention (92.1%) groups over 3 years. The study concluded that there was no difference in the effectiveness in preventing cavitated dentine carious lesions in high-caries risk occlusal surfaces of first permanent molars between daily supervised tooth brushing at school premises and sealing, either with CR or HVGIC in conjunction with the ART approach over a period of 3 years.

Chapter 5 describes an investigation of the cumulative survival of retained composite resin (CR) and HVGIC ART sealants over 3 years. A total of 123 schoolchildren, 6-7 years old, with high-caries risk pits and fissures in first permanent molars were included in this cluster-randomised clinical trial and treated with CR or HVGIC sealants according to the ART approach. Evaluations were performed after 0.5y, 1y, 2y and 3y by two independent and calibrated examiners. Retention was scored for free-smooth surface and for each of the three sections into which the occlusal surface had been divided. Survival of retained sealants was calculated using two criteria: the traditional criterion that fails a sealant when it is completely lost and the modified criterion that failed a sealant when at least one section (one third) of the occlusal surface was re-exposed to the oral environment. Cumulative survival rates of both CR and HVGIC ART sealants decreased over the 3-year period and the cumulative survival rates of retained CR and ART sealants for both occlusal and free-smooth surfaces were not significantly different from each other. However, CR retention rates were significantly higher at longer evaluation intervals. These results were no different for the two retention assessment criteria. The modified retention criterion presented significantly lower retention rates than the traditional one. The use of retention as a surrogate endpoint to determine sealant effectiveness is questioned.

In **Chapter 6** the hypothesis tested is that, in the initial high-caries-risk children of the trial, the supervised tooth brushing (STB) of the UCT oral healthcare protocol (UCT/STB) will

present a greater reduction in levels of visible plaque and gingival bleeding than peers that belong to the no supervised tooth brushing protocol (NSTB) of the CRT and ART oral healthcare protocols (CRT+ART/NSTB), and to an initial low-caries-risk NSTB group (dmft≤1), which received no treatment at all other than instructions on how to clean teeth and choose healthy food (No-Treatment/NSTB) over 4 years. A total of 273 children were examined at baseline (T_0) and after 4 years (T_1) according to the VPI and the GBI index. Data were analysed using linear (mean VPI at T_1) and logistic regression (mean GBI at T_1) with UCT/STB as the reference and 'mean VPI at T_0', 'mean GBI at T_0', 'combined CRT+ART/NSTB' and 'No-treatment/NSTB' as (co) variables. The analyses showed that: (1) the mean VPI and mean GBI scores were statistically significantly lower at T_1 than at T_0; (2) the reduction in mean VPI scores in children of the UCT/STB protocol was statistically significantly higher than for the CRT+ART/NSTB children over the 4-year period but no difference was observed between UCT/STB and 'No-treatment/NSTB' children; and (3) no statistically significant differences in reduction of mean GBI scores were observed between the studied groups over 4 years. It was concluded that a higher reduction in visible plaque levels was present in children of the UCT/STB group than in those belonging to the CRT+ART/NSTB group over the 4 years.

8.2 Samenvatting

Dit proefschrift is gebaseerd op vijf onderzoeken die de effectiviteit van verschillende mondzorgprotocollen onderzochten. De protocollen hadden betrekking op de preventie en de restauratieve behandeling van carieuze laesies in de gemengde dentitie van 6-7-jarige schoolkinderen uit Paranoa, een voorstad van Brasilia met een laag sociale status.

In **Hoofdstuk 1** wordt de inhoud van de zgn. Paranoa-Studie beschreven, alsmede de redenen en de doelstellingen van dit proefschrift. De Paranoa-Studie bevat verschillende onderzoeksterreinen zoals epidemiologie, tandartsangst, kwaliteit van leven, preventieve en restauratieve behandelingen, kosten-baten van de behandelprotocollen en laboratorium onderzoeken. Het eerste onderzoek van de Paranoa-Studie werd in 2009 uitgevoerd en betrof een epidemiologisch onderzoek naar de mondgezondheid van 6-7-jarigen. De prevalentie en ernst van tandcariës onder deze schoolkinderen was hoog. Ze hadden ook veel onbehandelde dentinecaviteiten. Om deze situatie te verbeteren moesten preventie en behandelprotocollen ontwikkeld worden die de huidige aandoeningen, m.n. in de tijdelijke dentitie, adequaat zouden bestrijden en nieuwe carieuze laesies m.n. in de blijvende dentitie, moesten voorkomen. Verder dienden de protocollen er voor te zorgen dat de mondzorg toegankelijker werd voor de lokale bevolking.

Deze zorgprotocollen bestaan uit een restauratief en preventief deel. Het betreft de 1) conventionele restauratieve aanpak (CRT) met amalgaam als vulmateriaal voor het restaureren van tijdelijke elementen, en het verzegelen van hoog cariësrisico putten en fissuren in eerste blijvende molaren met een composiet (CR); 2) de ART aanpak (ART) met hooggevuld glasionomeer als vulmateriaal voor het restaureren van tijdelijke elementen en voor het verzegelen van hoog cariësrisico putten en fissuren in eerste blijvende molaren en; 3) het schoonpoetsen met borstel en tandpasta van grote en middelgrote dentinecaviteiten, soms nadat de caviteit met handinstrumenten beter toegankelijk is gemaakt, en het restaureren van kleine dentinecaviteiten d.m.v. de ART aanpak (UCT). Het preventieve deel van dit behandelprotocol bestaat uit het consequent verwijderen van biofilm uit de hoog cariësrisico occlusale vlakken met borstel en tandpaste onder supervisie van een assistente tijdens schooluren (STB). De putten en fissuren werden dus niet verzegeld. Het CRT/CR protocol was de controlegroep en de ART en UCT/STB protocollen waren de testgroepen.

De eerste studie van dit proefschrift onderzocht de hypothese dat ART restauraties in

tijdelijke elementen langer zullen overleven dan amalgaam restauraties over een periode van 3 jaar (**Hoofdstuk 2**). Hiervoor werd een gerandomiseerd klinisch onderzoek opgezet waaraan 280 kinderen van 6 en 7 jaar deelnamen, die tenminste twee dentinecaviteiten in hun tijdelijk gebit hadden die niet pijnlijk waren en waarvan de pulpa nog intact was. In totaal plaatsten drie ervaren kindertandartsen bij respectievelijk 126 en 154 kinderen, 364 amalgaam en 386 ART restauraties. De evaluatie vond plaats na 6 maanden, en na 1, 2 en 3 jaar door dezelfde twee kindertandartsen die onderwezen en gekalibreerd waren in het gebruik van de ART restauratie evaluatiecriteria en de ICDAS index, maar geen restauraties hadden geplaatst. De cumulatieve 3-jaar overlevingspercentages van alle amalgaamrestauraties te samen (72.6%), die van eenvlaks (93.4%) en van meervlaks amalgaamrestauraties (64.7%) verschilden niet significant van alle ART restauraties (66.8%), eenvlaks ART (90.1) en meervlaks ART restauraties (56.4%). Meervlaksrestauraties vertoonden een significant lager cumulatief overlevingspercentage dan eenvlaksrestauraties voor beide protocollen. Mechanische redenen vormden de basis voor het mislukken van het overgrote deel van de restauraties (94.8%). Er was geen verschil in de redenen van mislukken tussen restauraties van beide protocollen. De cumulatieve overlevingspercentages voor eenvlaks en meervlaks ART restauraties waren hoger dan die in de laatste meta-analyse over ART restauraties staan vermeld. De reden hiervoor zou kunnen zijn dat het gebruikte hooggevuld glasionomeer betere eigenschappen heeft dan de wat oudere glasionomeren uit de onderzoeken van de meta-analyse. Het resultaat dat slechts 64.7% van de amalgaam en 56.4% van de ART meervlaksrestauraties overleefden, toont aan dat verbetering noodzakelijk is. De conclusie is dat de ART aanpak een rendabel alternatief is voor de conventionele amalgaamrestauratie in eenvlakscaviteiten, maar niet beter is in het restaureren van meervlakscaviteiten in tijdelijke molaren.

Bij de 2-jaars evaluatie werden zowel ART als CRT restauraties in de tijdelijke dentitie als mislukt aangemerkt, terwijl de beoordelaars ervan overtuigd waren dat deze elementen zonder problemen en klachten zouden exfoliëren. Deze observatie was de aanleiding om een secondaire analyse van het databestand uit hoofdstuk 2 uit te voeren met als doel de overleving van restauraties, die als goed en als mislukt waren beoordeeld, te berekenen (**Hoofdstuk 3**). De gegevens van alle gerestaureerde tijdelijke molaren, die na 6 maanden geëvalueerd waren, vormden de basis van deze analyse. Van de 681 gerestaureerde tijdelijke molaren werden er 487 aangemerkt als goed en 162 als mislukt. Deze elementen werden 3,5 jaar lang elk jaar gevolgd waarbij elementen die pijn veroorzaakten en elementen die tot

sepsis leidde als mislukt werden beschouwd. Het overlevingspercentage van tijdelijke molaren met een goede restauratie (97.5%) was na 2 jaar significant hoger dan dat van de restauraties die bij aanvang een defect vertoonden (75.9%). Er was geen significant verschil tussen de twee protocollen en tussen eenvlaks- of meervlaksrestauraties. Het overlevingspercentage van tijdelijke molaren met een mislukte restauratie over de periode van 2 jaar was hoog. Dit resultaat geeft aanleiding om te debatteren over de vraag of en wanneer het opnieuw restaureren van mislukte restauraties in tijdelijke molaren op deze leeftijd nodig is.

In **Hoofdstuk 4** wordt de effectiviteit van de drie tandcariës gerelateerde preventieve protocollen in een cluster gerandomiseerd klinisch onderzoek, onderzocht. Het onderzoek was gericht op hoog en laag cariësrisico-houdende occlusale vlakken van eerste blijvende molaren. In totaal werden 242 kinderen van 6 en 7 jaar uit Paranoa met een hoog cariësrisico, gemeten op het niveau van het kind, geïncludeerd. Daarna werd het cariësrisico van het occlusale vlak van de eerste blijvende molaren bepaald. Hiervoor werd de morfologie van putten en fissuren, en de aanwezigheid van carieuze glazuurlaesies als maat gebruikt. De occlusale vlakken werden voorzien van een composiet sealant (CR), een ART sealant (ART) of werden gepoetst met borstel en tandpasta onder supervisie gedurende de 200 schooldagen per jaar (STB). Laag cariësrisico occlusale vlakken werden volgens de STB aanpak mee schoongepoetst of kregen geen poets interventie (CR en ART kinderen). Twee onafhankelijke en gekalibreerde beoordelaars evalueerden alle molaren na 6 maanden, 1, 2 en 3 jaar. De aanwezigheid van een gecaviteerde carieuze dentinelaesie was het faalcriterium. De 3-jaar cumulatieve overlevingspercentages waren 95.6% (STB), 91.4% (CR) en 90.2% (ART) en verschilden onderling niet significant. Er bleek ook geen significant verschil te zijn tussen de 3-jaar cumulatieve overlevingspercentages voor de occlusale vlakken met een laag cariësrisico die met de STB (94.8%) werden behandeld en de occlusale vlakken die geen interventie hadden ondergaan (92.1%). De conclusie was dat, over een periode van 3 jaar bij deze 6 en 7 jarigen, het schoonpoetsen met borstel en tandpasta van occlusale vlakken met een hoog cariësrisico hetzelfde hoge resultaat oplevert dan het verzegelen van deze vlakken met een composiet of met een hooggevuld glasionomeer volgens de ART methode.

In **Hoofdstuk 5** wordt, bij dezelfde kinderen uit het onderzoek dat in hoofdstuk 4 is beschreven, de mate van retentie van composiet en ART verzegelingen onderzocht. Niet alleen verzegelingen in occlusale vlakken werden beoordeeld maar ook verzegelingen in putten en/of fissuren van gladde vlakken. Voor het berekenen van de retentie van

verzegelingen werd het occlusale vlak in drie gelijke delen verdeeld. Dit werd gedaan omdat het onderzoek ook een nieuwe methode voor het bepalen van retentie onderzocht. In tegenstelling tot de traditionele methode, die een verzegeling als mislukt beschouwd als er geen materiaal klinisch zichtbaar is, faalt de gemodificeerde methode een verzegeling voor retentie indien het verzegelingsmateriaal volledig van een van de drie delen van het occlusale vlak verdwenen is. De cumulatieve overlevingspercentages van behouden composiet en ART verzegelingen voor zowel de occlusale als voor de gladde vlakken verschilden niet significant van elkaar. Dit resultaat gold voor beide methoden voor het bepalen van de retentie. De cumulatieve overlevingspercentages waren significant lager voor de gemodificeerde dan voor de traditionele methode. Ondanks de relatief lage retentiegraad van de verzegelingen na 3 jaar blijkt het percentage gecaviteerde carieuze dentinelaesies in die periode laag te zijn. Het wordt verondersteld dat de verzegelingen een meerwaarde hebben bij kinderen met occlusale vlakken die een hoog cariësrisico hebben. Verder wordt getwijfeld of retentie van verzegelingen wel een surrogaat eindpunt kan worden genoemd in het bepalen van de effectiviteit van verzegelingen.

In **Hoofdstuk 6** wordt de hypothese getoetst dat, na 4 jaar, de reductie van zichtbare tandplaque en tandvleesbloeding significant hoger is bij de hoog cariësrisico kinderen met hoog cariësrisico occlusale vlakken uit de Paranoa-Studie, wiens tanden en kiezen onder supervisie werden gepoetst (STB), dan bij de hoog cariës-risico kinderen wiens tanden en kiezen niet onder supervisie werden gepoetst maar waar hoog cariësrisico occlusale vlakken waren verzegeld (NSTB). De hypothese werd ook getoetst bij laag cariës-risico kinderen die in het begin van deelname aan de Studie waren uitgesloten omdat ze niet aan de inclusiecriteria voldeden (Geen behandeling/NSTB). In totaal werden 273 kinderen aan het begin van het onderzoek (T0) en na 4 jaar (T1) onderzocht door gebruik te maken van de Visible Plaque Index (VPI) en de Gingival Bleeding Index (GBI). De gegevens werden door middel van de lineaire (gemiddelde VPI op T1) en de logistieke regressie (gemiddelde GBI op T1) methode geanalyseerd waarbij STB als referentie fungeerde en de ‘gemiddelde VPI op T0’, de ‘ gemiddelde GBI op T0’, ‘NSTB’ en ‘Geen-behandeling/NSTB’ de (co) variabelen waren. De analysen toonden aan dat na 4 jaar: 1) de gemiddelde VPI en de gemiddelde GBI op T1 statistisch significant lager waren dan op T0; 2) de reductie van de gemiddelde VPI waarden bij kinderen uit de STB groep statistisch significant hoger was dan bij kinderen uit de NSTB groep, maar dat er geen statistisch significant verschil was waargenomen tussen de STB kinderen en

de kinderen uit de Geen-behandeling/NSTB groep; 3) geen statistisch significant verschil was waargenomen in de reductie van de gemiddelde GBI waarden tussen de onderscheiden groepen kinderen. De conclusie was dat, na 4 jaar, de mate van reductie van zichtbare tandplaque hoger was bij kinderen uit de STB dan bij kinderen uit de NSTB en de Geen-behandeling/NSTB groepen

8.3 Conclusies

Op basis van de belangrijkste bevindingen in dit proefschrift kunnen de volgende conclusies getrokken worden.

1. Er was geen significant verschil in de overlevingspercentages van amalgaam en ART restoraties met een hooggevuld glasionomeer in tijdelijke molaren van 6 en 7 jarigen over een periode van 3 jaar (Hoofdstuk 2).
2. De overleving van meervlaksrestauraties voor beide protocollen was lager dan die van eenvlaksrestauraties (Hoofdstuk 2).
3. De overleving van tijdelijke molaren met een mislukte restauratie was hoog. Toch werden deze molaren significant vaker geëxtraheerd dan tijdelijke molaren met een goede restauratie over een periode van 2 jaar (Hoofdstuk 3).
4. Er was geen significant verschil in het voorkomen van gecaviteerde carieuze dentinelaesie tussen het schoonpoetsen met borstel en tandpasta van occlusale vlakken in eerste blijvende molaren van 6 en 7 jarigen met een hoog cariësrisico in vergelijking met het verzegelen van deze vlakken met een composiet of een hooggevuld glasionomeer volgens de ART methode (Hoofdstuk 4).
5. Er bleek geen significant verschil te bestaan, na 3 jaar, in het voorkomen van gecaviteerde carieuze dentinelaesie in de occlusale vlakken met een laag cariësrisico, die onder supervisie waren schoongepoetst, en de occlusale vlakken die geen behandelinterventie hadden ondergaan (Hoofdstuk 4).
6. De 3-jaar cumulatieve overlevingspercentages van behouden composiet en ART verzegelingen voor zowel de occlusale als voor de gladde vlakken verschilden niet significant van elkaar bij deze 6 en 7 jarigen (Hoofdstuk 5).
7. De kinderen die behandeld waren volgens een preventief mondzorgprotocol bestaande uit

dagelijks tandenpoetsen onder supervisie op school (UCT/STB) hadden een statistisch significant hogere reductie in zichtbare tandplaque na 4 jaar dan de kinderen die behandeld waren volgens een protocol dat gebaseerd was op het plaatsen van restauraties en het leggen van verzegelingen zonder supervisie van het poetsen van tanden en kiezen van de 6 en 7 jarigen (CRT/CR en ART) (Hoofdstuk 6).

8.4 Aanbevelingen

1. Het restaureren van dentinecaviteiten in tijdelijke elementen is de meest geaccepteerde behandeling voor dit type laesie. Dit proefschrift toont aan dat er geen verschil is in overlevingspercentages tussen restauraties met amalgaam en restauraties die volgens de ART methode met hooggevuld glasionomeer zijn gedaan over een periode van 3 jaar. Omdat ART minder tandartsenangst oproept en een minder pijnlijke behandeling is, goedkoper lijkt te zijn dan traditionele behandelingen, minder apparatuur vergt en daardoor beter in staat is om zorg op meer plaatsen te brengen, moet ART de standaard behandeling voor dentinecaviteiten in tijdelijke elementen worden. De ART aanpak moet geïntroduceerd worden in alle gouvernementele mondzorgklinieken en tandheelkundige onderwijsinstituten in Brazilië en de rest van de wereld. Onderwijsmateriaal voor en onderwijs in de ART methode dient verbeterd te worden en moet beschikbaar worden gesteld binnen geheel Brazilië.
2. De twee alternatieve mondzorgprotocollen die in dit proefschrift onderzocht zijn, bleken even goede resultaten op te leveren als de traditionele wijze van behandelen van carieuze laesies door middel van amalgaam restauraties en composiet verzegelingen, zoals die in de gouvernementele mondzorgklinieken van Brazilië toegepast worden. Echter, men moet ervan uitgaan dat de meeste gouvernementele tandartsen niet of onvoldoende onderwezen zijn in het gebruik van ART en dat het in de studie gebruikte hooggevuld glasionomeer niet in hun kliniek aanwezig is. Daarom is het nodig om deze tandartsen in ART te onderwijzen en ervoor te zorgen dat kwalitatief goed hooggevuld glasionomeer in de klinieken aanwezig is, alvorens de tandartsen voor het bijwonen van een cursus uit te nodigen.
3. Om beter te kunnen beoordelen of en wanneer het nodig is om mislukte restauraties in tijdelijke elementen te vervangen of te repareren moet toekomstig onderzoek hiernaar niet

alleen belang hechten aan de overleving van de restauraties maar ook aan de overleving van de elementen. Het is ook belangrijk om de invloed van mislukte restauraties op het patroon van exfoliëren van deze gebitselementen en de kwaliteit van leven van de kinderen te onderzoeken.

4. Het verzegelen van hoog cariësrisico putten en fissuren in blijvende molaren bij kinderen met een hoog cariësrisico is geïndiceerd, indien een gesuperviseerd poetsprogramma afwezig is. Het type verzegeling, of composiet of glasionomeer ART, heeft geen invloed op de mate waarin gecaviteerde carieuze dentinelaesies worden voorkomen. Aangezien het gebruik van ART verzegeling de toegang tot preventieve zorg vermeerdert, omdat geen apparatuur nodig is en omdat het hooggevuld glasionomeer minder vochtgevoelig is dan composiet, zijn ART verzegelingen de eerste keuze.
5. Het UCT mondzorgprotocol was even effectief als de CRT en ART mondzorgprotocollen voor het behandelen van dentinecaviteiten in tijdelijke molaren en voor het voorkomen van gecaviteerde carieuze dentinelaesies in occlusale vlakken van eerste blijvende molaren. Een bijkomend gunstig effect was dat kinderen uit de UCT protocolgroep een hogere reductie in zichtbare tandplaque na 4 jaar vertoonden dan de kinderen uit de twee andere protocolgroepen. Omdat slechts enkele onderzoeken zijn uitgevoerd naar de effectiviteit van het verwijderen van tandplaque uit open caviteiten, is meer onderzoek nodig voordat dit protocol kan worden aanbevolen. Desalniettemin is het belangrijk dat de resultaten van deze studie onder de collega's worden verspreid en niet alleen in Brazilië maar ook daarbuiten.

8.5 Resumo

A presente tese de PhD (Doctor of Philosophy) é baseada em cinco estudos que procuraram investigar a efetividade de diferentes protocolos de cuidado em saúde bucal na prevenção e no tratamento de lesões cariosas na dentição mista de escolares de 6-7 anos de idade no Paranoá.

O **Capítulo 1** apresenta o "Estudo do Paranoá", sua lógica e os objetivos da presente tese. O Estudo do Paranoá cobre vários tópicos de pesquisa distintos tais como epidemiologia, ansiedade e dor frente ao tratamento odontológico, qualidade de vida, tratamentos restauradores, prevenção da cárie, custo-efetividade e investigações laboratoriais. O estudo iniciou investigando a situação de saúde bucal das crianças do Paranoá, uma área da periferia de Brasília que apresenta um índice de desenvolvimento humano abaixo da média da capital do Brasil. O levantamento epidemiológico de saúde bucal conduzido em 2009 revelou que escolares de 6 -7 anos de idade apresentavam uma alta prevalência de cárie nas dentições decídua e permanente e uma alta experiência média de cárie na dentição decídua. Também, demonstrou que a maioria das lesões cariosas cavitadas em dentina em dentes decíduos não era tratadas. A situação incentivou o desenvolvimento e a pesquisa de protocolos de cuidado em saúde bucal que proporcionassem tratamento para as lesões cariosas existentes nos dentes decíduos e que pudessem prevenir novas lesões cariosas, especialmente na dentição permanente em erupção. Além do mais, os protocolos de cuidado em saúde bucal precisariam ser de mais fácil acesso para a população desta área desfavorecida.

Os protocolos de cuidado em saúde bucal investigados no estudo do Paranoá foram:

Tratamento Restaurador Convencional (CRT), que consistiu da restauração dos molares decíduos usando instrumentos rotatórios e amálgama, e do selamento das superfícies de alto risco à cárie dos primeiros molares permanentes utilizando selantes resinosos;

Tratamento Restaurador Atraumático (ART), que consistiu da restauração os molares decíduos com um cimento de ionômero de vidro de alta viscosidade (HVGIC) de acordo com a técnica do ART, e do selamento das superfícies de alto risco à cárie de primeiros molares permanentes com selantes HVGIC ART; e,

Tratamento Ultra Conservador (UCT), que consistiu da restauração de pequenas cavidades não passíveis de limpeza em dentes decíduos utilizando o ART e no qual cavidades médias e grandes ficaram abertas, sendo tais cavidades ampliadas quando necessário para

permitir o acesso à limpeza. A limpeza das cavidades (e dos dentes em geral) foi realizada com escova dental e dentifrício fluoretado, nas escolas, sob supervisão diária, durante o período letivo. As superfícies de alto risco à cárie de primeiros molares permanentes foram limpas durante estas atividades, mas não foram realizados selantes.

O protocolo de cuidado em saúde bucal CRT foi considerado o grupo controle e os protocolos ART e UCT, os grupos teste. O **Capítulo 1** também apresenta resultados de outras pesquisas do Estudo do Paranoá já realizadas. Finalmente, a lógica e os objetivos do PhD são descritos. Os objetivos foram: (1) comparar as taxas cumulativas de sobrevida de restaurações de amálgama e ART em molares decíduos por um período de três anos; (2) comparar as taxas de sobrevida de molares decíduos com restaurações intactas e defeituosas de amálgama e ART; (3) comparar a efetividade de dois tipos de selante e da escovação supervisionada (STB) na prevenção do desenvolvimento de lesões cariosas em dentina em superfícies oclusais de alto e baixo risco à carie de primeiros molares permanentes por três anos; (4) comparar a taxa cumulativa de retenção de selantes resinosos e de selantes ART com ionômero de vidro de alta viscosidade em primeiros molares permanentes por um período de três anos utilizando dois critérios de avaliação da retenção; e (5) avaliar a efetividade da escovação supervisionada nos níveis de biofilme e de sangramento gengival comparados à escovação não-supervisionada, por um período de quatro anos.

Observar se restaurações ART com ionômero de vidro de alta viscosidade se comportam melhor do que restaurações CRT em molares decíduos foi o objetivo do estudo apresentado no **Capítulo 2**. O estudo foi um ensaio clínico randomizado por conglomerados utilizando um desenho de grupos paralelos que comparou as taxas cumulativas de sobrevida de restaurações de amálgama e ART em molares decíduos por três anos. Um total de 280 crianças de 6-7 anos de idade e que apresentavam ao menos duas lesões cariosas cavitadas em dentina em molares decíduos sem dor ou envolvimento pulpar foram incluídas no estudo. Um total de 364 restaurações de amálgama (em 126 crianças) e 386 restaurações ART (em 154 crianças) foram realizadas por três odontopediatras treinados e calibrados e avaliadas após 0,5, 1, 2 e 3 anos, utilizando o critério de restaurações ART, por dois examinadores independentes e calibrados. As taxas cumulativas de sobrevida no decorrer de três anos para todas as restaurações de amálgama (72,6%), restaurações de amálgama envolvendo uma face (93,4%) e envolvendo múltiplas faces (64,7%) não foram diferentes de restaurações ART comparáveis (76,8%; 90,1% e 56,4%, respectivamente). Restaurações envolvendo múltiplas faces

apresentaram uma sobrevida significativamente mais baixa do que restaurações envolvendo uma face para ambos protocolos restauradores. As razões mais comuns para falhas restauradoras foram mecânicas (94,8%), enquanto cárie secundária foi o motivo de falha em apenas 5,2% dos casos. Não foram observadas diferenças entre as razões para falhas entre os protocolos restauradores testados. As taxas de sobrevida de restaurações ART envolvendo uma face e múltiplas faces foi superior do que as de uma meta-análise sobre restaurações ART (66% e 31%, respectivamente). Isto era esperado e pode ser atribuído ao uso de um novo ionômero de vidro de alta viscosidade (novo na época em que o estudo foi iniciado) com uma razão pó-líquido mais alta do que o usual e melhores propriedades mecânicas. Entretanto, no específico intervalo de três anos, restaurações de amálgama de múltiplas faces apresentaram taxas de sobrevida significativamente mais altas do que restaurações ART comparáveis. A taxa de falha de 43,6% em restaurações ART envolvendo múltiplas faces aos três anos *versus* 35,3% para restaurações de amálgama indica que aprimoramentos nas restaurações ART ainda são necessários. O estudo conclui que o uso do ionômero de vidro de alta viscosidade segundo a técnica ART pode ser considerado uma alternativa viável às convencionais restaurações de amálgama para restaurar cavidades envolvendo uma face em molares decíduos.

Durante as avaliações do ensaio clínico supracitado notou-se que um grande número de restaurações defeituosas não causaram nenhum problema para as crianças, nem foram muitos os dentes diagnosticados com abscesso ou fístula. Isso gerou a pergunta se dentes com restaurações defeituosas realmente precisariam ser re-restaurados, o que é o protocolo mais comumente aceito, uma vez que haveria uma grande chance de tais dentes esfoliarem sem dor ou sepse. Assim, análises adicionais que compararam as taxas de sobrevida de molares decíduos com restaurações intactas e defeituosas de amálgama e ART foram executadas (**Capítulo 3**). 649 molares decíduos restaurados, dos quais 162 foram avaliados com restaurações defeituosas por razoes mecânicas foram acompanhados por um período de 3,5 anos. Dentes com restaurações defeituosas foram analisados a partir do momento em que a restauração foi julgada com problemas. Os molares decíduos restaurados que precisaram ser extraídos devido à presença de sepse ou dor foram considerados falhas. A taxa de sobrevida de molares decíduos com restaurações intactas (97,5%) foi significativamente maior do que a dos molares com restaurações defeituosas (75,9%) no decorrer de um período de 2 anos. Não foi observado efeito do protocolo de tratamento (amálgama ou ART) ou do número de faces envolvidas (uma ou múltiplas). Concluiu-se que apesar da taxa mais alta de extrações nos

molares decíduos com restaurações defeituosas do que nos molares com restaurações intactas, a taxa de sobrevida foi alta tanto para os dentes com restaurações defeituosas como para os dentes com restaurações intactas. Isso sugere que a decisão de re-restaurar restaurações defeituosas em dentes decíduos precisa tornar-se tópico de discussão.

O **Capítulo 4** apresenta um ensaio clínico randomizado por conglomerados que teve como objetivo investigar a efetividade de três protocolos de prevenção de cárie em superfícies oclusais de alto e baixo risco à cárie de primeiros molares permanentes por três anos. 242 escolares de 6-7 anos de idade da região de baixo nível socioeconômico do Paranoá e apresentando um alto risco à cárie em nível de paciente foram incluídos no estudo. Inicialmente, fóssulas e fissuras de primeiros molares permanentes foram avaliadas quanto ao risco à cárie em nível de superfície dental usando uma combinação do ICDAS II e da profundidade de fissura (alto risco à cárie foi determinado por códigos ICDAS II 2 e 3 ou pela combinação de códigos ICDAS II 1 e fissuras médias ou profundas). Superfícies oclusais de alto risco à cárie foram tratadas de acordo com três protocolos: escovação supervisionada diária na escola (STB), selante resinoso (CR) e selante ART com ionômero de vidro de alta viscosidade. Superfícies oclusais de baixo risco à cárie receberam STB ou nenhuma intervenção. Dois examinadores independentes e calibrados avaliaram as crianças em 0,5, 1, 2 e 3 anos. Uma lesão cariosa cavitada em dentina foi considerada como falha. No decorrer de três anos, não houve diferença significativa entre os grupos nas taxas cumulativas de sobrevida de superfícies oclusais de alto risco à cárie livres de lesões cariosas cavitadas em dentina. Taxas cumulativas de sobrevida foram 95,6%, 91,4% e 90,2% para STB, selantes resinosos e selantes ART, respectivamente. Para superfícies oclusais de baixo risco à cárie não foi observada diferença entre as taxas cumulativas de sobrevida de superfícies livres de lesão cariosa cavitada em dentina entre STB (94,8%) e nenhuma intervenção (92,1%) no decorrer de três anos. O estudo concluiu que não há diferença na efetividade de prevenção de lesões cariosas cavitadas em dentina em superfícies oclusais de alto risco à cárie em primeiros molares permanentes entre escovação supervisionada diária na escola e selantes, independentemente se resinosos ou com ionômero de vidro de alta viscosidade em conjunto com a técnica ART no decorrer de um período de três anos.

O **Capítulo 5** descreve uma investigação sobre as taxas cumulativas de retenção de selantes resinosos (CR) e selantes ART com ionômero de vidro de alta viscosidade acompanhados por três anos. Um total de 123 escolares de 6-7 anos de idade com fóssulas e

fissuras de alto risco à cárie em primeiros molares permanentes foram incluídos nesse ensaio clínico randomizado por conglomerados e tratados com selantes CR e selantes ART. Foram realizadas avaliações após 0,5, 1, 2 e 3 anos por dois examinadores independentes e calibrados. Escores de retenção foram registrados para as superfícies lisas livres e para cada uma de três secções nas quais a superfície oclusal foi dividida. A sobrevida de selantes retidos foi calculada usando dois critérios: o critério tradicional, que falha um selante para retenção quando este é completamente perdido; e, o critério modificado, que falha um selante para retenção quando ao menos uma secção (um terço) da superfície oclusal foi reexposta ao meio bucal. Taxas cumulativas de retenção para ambos selantes resinosos e ART diminuíram no decorrer do período de três anos e as taxas cumulativas de retenção dos selantes resinosos e ART para ambas superfícies oclusal e lisas livres não foram significativamente diferentes entre si. Entretanto, as taxas de retenção dos selantes resinosos foram significativamente mais altas em intervalos de avaliação mais longos. Estes resultados não foram diferentes para os dois critérios de avaliação de retenção estudados. O critério modificado apresentou taxas de retenção significativamente mais baixas do que o critério tradicional. O uso da retenção como um método alternativo para determinar a efetividade de um selante é questionado.

No **Capítulo 6** a hipótese testada foi a de que em crianças inicialmente com alto risco à cárie, a escovação supervisionada (STB) do protocolo de cuidado em saúde bucal UCT (UCT/STB) apresentaria uma maior redução nos níveis de placa visível e sangramento gengival do que crianças sem a escovação supervisionada (NSTB) pertencentes aos protocolos de cuidado em saúde bucal CRT e ART (CRT+ART/NSTB) e do que um grupo sem escovação supervisionada incialmente de baixo risco à cárie (ceo-d≤1) que não receberam qualquer tratamento além de instruções básicas em higiene oral e nutrição saudável (No-treatment/NSTB) . Um total de 273 crianças foi examinado no *baseline* (T_0) e após 4 anos (T_1) de acordo com os índices de placa visível (VPI) e sangramento gengival (GBI). Os dados foram analisados usando regressão linear (VPI médio em T_1) e regressão logística (GBI médio em T_1) com o grupo UCT/STB como referência e "VPI médio em T_0", "GBI médio em T_0", "CRT+ART/NSTB" e "No-treatment/NSTB" como covariáveis. As análises demonstraram que: (1) os escores médios de VPI e GBI foram significativamente mais baixos em T_1 do que em T_0, (2) a redução nos escores médios de VPI nas crianças do protocolo UCT/STB foi significativamente maior do que para as crianças do protocolo CRT+ART/NSTB no período de quatro anos, mas não foi observada diferença entre crianças do UCT/STB e do No-

treatment/NSTB; e (3) não foram observadas diferenças significativas na redução dos escores médios de GBI entre os grupos estudados após quatro anos. Conclui-se que uma maior redução nos níveis de placa visível ocorreu nas crianças do grupo UCT/STB do que naquelas pertencentes ao grupo CRT+ART/NSTB após quatro anos.

8.6 Conclusões

Com base nos principais resultados desta pesquisa de PhD é possível concluir:

1. Não houve diferença nas taxas cumulativas de sobrevida de restaurações convencionais de amálgama e restaurações ART com um ionômero de vidro de alta viscosidade em molares decíduos de crianças de 6-7 anos de idade no decorrer de três anos (Capítulo 2);
2. Restaurações convencionais e restaurações ART envolvendo múltiplas faces em molares decíduos apresentaram taxas cumulativas de sobrevida mais baixas do que restaurações envolvendo somente uma face (Capítulo 2);
3. Molares decíduos com restaurações defeituosas foram extraídos mais frequentemente do que dentes restaurados comparáveis com restaurações intactas. As taxas de sobrevida de molares decíduos tanto com restaurações defeituosas quanto intactas foram altas (Capítulo 3);
4. Não houve diferença no efeito preventivo de cárie de selantes resinosos, selantes ART usando ionômero de vidro de alta viscosidade e escovação supervisionada diária na escola em superfícies oclusais de alto risco à cárie em primeiros molares permanentes de crianças de 6-7 anos de idade no decorrer de três anos (Capítulo 4);
5. Em superfícies oclusais de alto risco à cárie de crianças de 6-7 anos de idade não foi observada diferença nas taxas cumulativas de sobrevida de superfícies livres de lesão cariosa cavitada em dentina entre escovação supervisionada diária na escola e nenhuma intervenção no decorrer de um período de três anos (Capítulo 4);
6. As taxas cumulativas de retenção não foram significativamente diferentes entre selantes resinosos e selantes ART com ionômero de vidro de alta viscosidade em superfícies oclusais de alto risco à cárie de primeiros molares permanentes de crianças de 6-7 anos de idade no decorrer de três anos. Uma retenção significativamente mais alta foi observada para os selantes resinosos em intervalos específicos de avaliação mais longos (Capítulo 5);

7. Crianças que foram submetidas a um protocolo de cuidado em saúde bucal que incluía escovação supervisionada diária na escola apresentaram uma maior redução nos níveis de placa visível do que crianças que receberam protocolos de cuidado em saúde bucal baseados em restaurações e selantes sem escovação supervisionada após quatro anos (Capítulo 6).

8.7 Recomendações

1. A restauração de lesões cariosas cavitadas em dentina em dentes decíduos é o tratamento mais aceito para estas lesões. A presente tese mostrou que restaurações convencionais de amálgama e restaurações ART com ionômero de vidro com alta viscosidade em molares decíduos sobrevivem de maneira similar no decorrer de três anos. Assim, uma vez que o ART é um procedimento mais acessível, que requer menos equipamentos, que causa menores níveis de dor e ansiedade e que parece ser mais barato do que as restaurações convencionais, ele deve tornar-se o procedimento restaurador padrão para dentes decíduos. A técnica do ART deve ser amplamente introduzida no serviço de saúde pública e nas instituições de ensino odontológico do Brasil e de outros países. Materiais de instrução e educação básica na técnica do ART devem ser aprimorados e amplamente difundidos no Brasil.
2. Os protocolos de cuidado em saúde bucal investigados nessa tese foram tão efetivos quanto a maneira convencional de tratar a cárie dental nos centros de saúde bucal públicos do Brasil, que é baseada na restauração de molares decíduos com amálgama e no selamento de primeiros molares permanentes com selantes resinosos. Entretanto, acredita-se que a maioria dos dentistas que atualmente trabalha no setor público não é adequadamente treinada na técnica ART, nem é o ionômero de vidro disponível nos centros de saúde de alta viscosidade. Assim, antes de implementar protocolos que dependam da técnica ART é preciso treinar a equipe de saúde bucal apropriadamente e disponibilizar a eles material de boa qualidade.
3. Para ajudar a entender quando e se é necessário re-restaurar ou reparar uma restauração defeituosa em um molar decíduo, futuros ensaios clínicos devem avaliar não apenas a sobrevida das restaurações, como também a sobrevida dos dentes, e devem examinar os

efeitos das restaurações defeituosas nos padrões de esfoliação e na qualidade de vida.

4. Selantes são indicados para superfícies de alto risco à cárie de molares permanentes de crianças de alto risco à cárie sempre que um programa intensivo e frequente de escovação supervisionada não estiver disponível. O tipo de selante, se resinoso ou ART com um ionômero de vidro de alta viscosidade, não parece influenciar no efeito preventivo de cárie. Assim, uma vez que a técnica ART aumenta a acessibilidade ao cuidado restaurador e preventivo e o ionômero de vidro de alta viscosidade é mais tolerante à umidade durante o processo de erupção dental, os selantes ART são a primeira escolha para o selamento de superfícies dentais sujeitas à cárie.
5. O protocolo de cuidado bucal UCT foi tão efetivo quanto os protocolos CRT e ART no tratamento de lesões cariosas cavitadas em dentina em molares decíduos e na prevenção de lesões cariosas cavitadas em dentina em primeiros molares permanentes. Como beneficio adicional, crianças do protocolo UCT apresentaram maior redução nos níveis de placa visível após quatro anos. Uma vez que são poucos os estudos que investigaram o efeito da remoção de placa de dentro de cavidades dentais, mais estudos desse tipo são necessários antes que o protocolo UCT possa ser considerado algo baseado em evidências. Não obstante, os resultados do protocolo UCT devem ser amplamente divulgados dentro e fora do Brasil.

ACKNOWLEDGEMENTS

My special thanks goes to dr. Jo Frencken. You are not just a superb scientific advisor, but also one of the best examples of hard-working, good friend and good counsellor one can have. You have taught and inspired so many, and your work has changed Dentistry and made oral healthcare accessible to those that needed it the most. It was an honour to be part of your 'team' and to learn from you. Thanks for the opportunities, for the incentives and for the inspiration to become a better researcher and teacher. May one day I teach (and inspire students) as half as good as you do.

'The teacher who walks in the shadow of the temple, among his followers, gives not of his wisdom but rather of his faith and his lovingness.
If he is indeed wise he does not bid you enter the house of his wisdom, but rather leads you to the threshold of your own mind.
The astronomer may speak to you of his understanding of space, but he cannot give you his understanding.
The musician may sing to you of the rhythm which is in all space, but he cannot give you the ear which arrests the rhythm nor the voice that echoes it.
And he who is versed in the science of numbers can tell of the regions of weight and measure, but he cannot conduct you thither.
For the vision of one man lends not its wings to another man.' (Kahlil Gibran)

To Prof. dr. Soraya Leal, my brilliant supervisor, dear friend and colleague, thanks for the invitation to work with you when I was a newly arrived faculty member of the University of Brasília more than six years ago. You believed in me and Ana, helped in creating conditions for us to settle in Brasília and a huge part of this thesis comes from your mind. May we keep working together for years to come.

To Prof. dr. Nico Creugers, thanks for the very competent PhD supervision, for the valuable and kind comments, inputs and suggestions on this thesis. It was a pleasure working with you.

My gratitude goes to the members of the Doctoral Thesis Committee, Prof. dr. M-C. Huysmans, Prof. dr. C. van Loveren, and Dr. A.J.P. van Strijp for the valuable suggestions in improving this thesis to its present final form.

My sincere appreciation goes to Mr. Jan Mulder for knowledgeably performing the statistical analyses of most of the studies presented in this thesis. Your availability, friendship, patience and experience on clinical trials were pillars that made this whole work possible. My

most sincere gratitude goes also to Dr. Ewald Bronkhorst that skillfully played a very important role on the understanding and analyses of data that made possible some of the final chapters of this thesis.

Thanks to Mrs. Janny Wijmega and Mrs. Dominique Niesten, who have always arranged all necessary details for my visits to Nijmegen. You have immensely cooperated to make those periods productive and unforgettable.

This thesis, as part of the 'Paranoá Study' could not be performed and written without the huge support of the whole team of the cooperation Nijmegen-Brasília. Jo, Soraya, Ana, Rodrigo, Dani, Maitê, Zezé, Gabriela, Luciana, Jorge, Rafael and Renata, thanks for creating such a true meaning for 'teamwork'.

To the Radboud University Nijmegen Medical Centre, my gratitude and honour for being a student in such a great and respected institution. Being to The Netherlands and getting to know the relevance and support that its people give to education and research makes it easy to understand the development and high standards of living of the country. May developing countries as Brazil follow such example and make of high-quality education its top priority.

Thanks to the University of Brasília that also supported this PhD thesis. A special thanks to my colleagues Patrícia, Ana Paula and Fernanda that assumed part of my teaching activities whenever needed so that I could focus on completing this thesis. I'm blessed by having such nice co-workers at UnB.

This whole thesis would not be possible without the cooperation of the Secretary of Education of the Federal District Government (Brasília, Brazil) that allowed us to work in the schools of Paranoá. My gratitude goes to all directors, teachers and staff of the schools. Your continuous help was fundamental for the research to be carried out. Thanks to FAPDF for the financial support, to ABCD for the logistic support and to the dental assistants Patricia and Helcira.

Above all, my gratitude goes to the participating children of the study. You have taught us so much. We wish (and work with the intention) that the findings of this thesis could somehow help you and the future generations to have a better oral health and an improved quality of life.

To all those friends and family not cited here but who have contributed directly or indirectly to this thesis, from those with words of support to those with a friendly smile, thank you for being an important part of my life.

To my in-law family Walter, Ivone, Nati, Grandma Hilma and all relatives, thanks so much for the enjoyable moments and constant support.

Thanks to my sister Mariana, for the fraternal love, support and encouragement.

Dear father Gaston and mother Tânia, every word of this thesis is a tribute to all your love and efforts in giving your children opportunities for growth. You are my role models and I am sure I will never be able to thank you for all you did and keep doing for me as much as you deserve.

Last, but not least, I want to express my deepest gratitude to my wife Ana Luiza. You are my soul mate and I cannot imagine anymore going through the daily challenges of life without you by my side. The PhD is a great example of something we dreamt together, worked together and accomplished together. All I want is to keep dreaming and seeing dreams come true with you. I love you!

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The prevalence of dental caries in children worldwide is very high. This PhD thesis investigated and compared the effectiveness of three oral healthcare protocols - the Conventional Restorative Treatment (CRT), the Atraumatic Restorative Treatment (ART), and the Ultra-conservative Treatment (UCT) - in preventing and treating dentine carious lesions in mixed-dentitions of 6-7-year-old schoolchildren from Paranoá, a deprived suburban area of Brasília, Brazil.

This thesis presents clinical trials regarding: the survival of CRT and ART restorations in primary molars; the survival of primary molars that presented intact and defective restorations; the caries-preventive effect of supervised tooth brushing, composite resin and ART sealants; the survival of retained composite resin and ART sealants using different assessment criteria; and the long-term effect of supervised tooth brushing on levels of visible plaque and gingival bleeding among schoolchildren.

The findings of this thesis support the use of ART restorations as a viable option to replace amalgam for managing cavitated dentine carious lesions in single-surfaces in primary molars and daily supervised tooth brushing at school and the application of ART sealants for preventing the occurrence of dentine carious lesions in first permanent molars. They further question the need to re-restore defective restorations in primary molars and show the benefit of supervised tooth brushing for obtaining a clean dentition in this age group.

Oral healthcare protocols that are more accessible to the populations and that act on the causes of the disease, such as ART and UCT, seem to be the best options to reduce the burden of dental caries and to improve children's oral health and quality of life.

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